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REPLIMUNE GROUP, INC. Financial Statements For the Years Ended March 31, 2019, 2018 and 2017

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended March 31, 2019

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number 001-38596

REPLIMUNE GROUP, INC.
(Exact name of registrant as specified in its charter)

Delaware	**82-2082553**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

18 Commerce Way
Woburn MA 01801
(Address of principal executive offices)
(Zip Code)

(781) 995-2443
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	REPL	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.045 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer o	Accelerated filer o	Non-accelerated filer ☒	Smaller reporting company o

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o No ☒

The aggregate market value of the Common Stock held by non-affiliates of the registrant was approximately $184 million, based on the closing price of the registrant's Common Stock on September 28, 2018, the last business day of the registrant's most recently completed second fiscal quarter.

There were 31,663,701 shares of Common Stock outstanding as of June 21, 2019.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended March 31, 2019. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

REPLIMUNE GROUP, INC.
ANNUAL REPORT ON FORM 10-K
For the Year Ended March 31, 2019

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Special note regarding forward-looking statements

This Annual Report on Form 10-K contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify these forward-looking statements by the use of words such as "outlook," "believes," "expects," "potential," "continues," "may," "will," "should," "seeks," "approximately," "predicts," "intends," "plans," "estimates," "anticipates" or the negative version of these words or other comparable words. Such forward-looking statements are subject to various risks and uncertainties. Accordingly, there are or will be important factors that could cause actual outcomes or results to differ materially from those indicated in these statements. We believe these factors include, among other things:

- the timing, progress, and results of preclinical studies and clinical trials for RP1 or any of our other product candidates, including the timing of initiation and completion of studies or trials and related preparatory work and the period during which the results of the trials will become available;
- our ability to obtain additional funding as necessary;
- the timing, scope or likelihood of regulatory filings and approvals, including timing of our Biologics License Application, or BLA, and filing for, and final approval by the Food and Drug Administration, or the FDA, of, RP1 or any of our other product candidates;
- the timing, scope, or likelihood of foreign regulatory filings and approvals;
- our ability to develop our product candidates for use in combination with other checkpoint blockade therapies, including anti-PD-1;
- our ability to develop and advance any future product candidates into, and successfully complete, clinical trials;
- our expectations regarding the size of the patient populations for RP1 or our other product candidates if approved for commercial use;
- the costs and timing of establishing, equipping, and operating our planned in-house manufacturing facility;
- our estimates regarding expenses and capital requirements;
- the implementation of our business model and our strategic plans for our business, RP1 and our other product candidates;
- the rate and degree of market acceptance and clinical utility of RP1 or our other product candidates;
- the potential benefits of and our ability to establish or maintain future collaborations or strategic relationships;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering RP1 and our other product candidates, claims others may make regarding rights in our intellectual property, and any potential infringement, misappropriation or other violation of any third-party intellectual property rights;
- our competitive position, and developments and projections relating to our competitors and our industry;

- negative developments in the field of immuno-oncology;
- the impact of laws and regulations;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012; and
- the other risks and uncertainties described under "Risk factors."

The forward-looking statements made in this Annual Report on Form 10-K relate only to events as of the date on which the statements are made. These factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements that are included in this Annual Report on Form 10-K. Moreover, we operate in a competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Annual Report on Form 10-K. We undertake no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except to the extent required by applicable law. You should not rely on forward-looking statements as predictions of future events. We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements.

PART I

Item 1. Business

Overview

We are a clinical-stage biotechnology company committed to applying our leading expertise in the field of oncolytic immunotherapy to transform the lives of cancer patients. We use our proprietary Immulytic platform to design and develop product candidates that are intended to maximally activate the immune system against cancer.

Oncolytic immunotherapy is an emerging class of cancer treatment that exploits the ability of certain viruses to selectively replicate in and directly kill tumors, as well as induce a potent, patient-specific, anti-tumor immune response. Such oncolytic, or "cancer killing," viruses have the potential to generate an immune response targeted to an individual patient's particular set of tumor antigens, including neo-antigens that are uniquely present in tumors. Our product candidates incorporate multiple mechanisms of action into a practical "off-the-shelf" approach that is intended to maximize the immune response against a patient's cancer and to offer significant advantages over personalized vaccine approaches. We believe that the bundling of multiple approaches for the treatment of cancer into single therapies will simplify the development path of our product candidates, while also improving patient outcomes at a lower cost to the healthcare system than the use of multiple different drugs.

The foundation of our Immulytic platform consists of a proprietary, engineered strain of herpes simplex virus 1, or HSV-1, that has been "armed" with a fusogenic protein intended to substantially increase anti-tumor activity. Our platform enables us to incorporate various genes whose expression is intended to augment the inherent properties of HSV-1 to both directly destroy tumor cells and induce an anti-tumor immune response. We believe our lead product candidate, RP1, will be effective at killing tumors and inducing immunogenic, or immune-stimulating, tumor cell death and that it will be highly synergistic with immune checkpoint blockade therapies.

We are currently conducting a Phase 1/2 clinical trial with RP1 in approximately 150 patients. We have completed enrollment of the Phase 1 dose rising part of this clinical trial in which we are assessing the safety and tolerability of RP1 administered alone in 22 patients with mixed advanced solid tumor types, and following the review of the data by the Safety Review Committee, or SRC, have determined the dose regimen to be administered in the Phase 2 part of this clinical trial. We are completing enrollment of a Phase 1 expansion cohort of approximately 12 patients in which we are assessing the safety and tolerability of RP1 administered in combination with an anti-PD1 therapy at the determined Phase 2 dose level. One patient with microsatellite instability high cancers, or MSI-H/dMMR, remains to be enrolled in the expansion cohort.

The Phase 2 part of this clinical trial is designed to assess the safety and efficacy of RP1 in combination with an anti-PD1 therapy in four cohorts of approximately 30 patients with melanoma, non-melanoma skin cancers, bladder cancer and MSI-H/dMMR. Following SRC review of the Phase 1 data to date, including data from the expansion cohort receiving RP1 with anti-PD1 therapy, we have opened enrollment in the United States and the United Kingdom of the melanoma, bladder cancer, and non-melanoma skin cancer Phase 2 cohorts, and will open enrollment of the MSI-H-dMMR Phase 2 cohort after a final evaluable MSI-H/dMMR patient has been enrolled in the Phase 1 expansion cohort without safety concerns. In the Phase 2 part of the clinical trial, we are also evaluating efficacy under the clinical trial protocol, primarily on the basis of the proportion of patients who have a response within each tumor type cohort. Responses are either defined as a partial response (a 30% or greater reduction in tumor size) or a complete response (a complete eradication of the disease). We then intend to analyze each cohort's data to determine the indications that merit progressing into further clinical development.

This Phase 1/2 clinical trial is being conducted as a collaboration with Bristol-Myers Squibb Company, or BMS, under which it has granted us a non-exclusive, royalty-free license to, and is supplying at no cost, its anti-PD-1 therapy, nivolumab, for use in combination with RP1 in this clinical trial. BMS has no further development-related obligations under this collaboration.

We have also entered into a collaboration agreement with Regeneron Pharmaceuticals, Inc., or Regeneron, under which we intend to conduct clinical development of our product candidates in combination with cemiplimab, an anti-PD-1 therapy developed by Regeneron. For each clinical trial conducted under this collaboration, Regeneron will fund one-half of the clinical trial costs, supply cemiplimab at no cost, and grant us a non-exclusive, royalty-free license to cemiplimab for use in the clinical trial. The first planned clinical trial under this collaboration is a randomized, controlled Phase 2 clinical trial of RP1 in combination with cemiplimab, versus cemiplimab alone, in approximately 240 patients with cutaneous squamous cell carcinoma, or CSCC. Initial study site activation is currently underway in the United States and Australia, with study initiation expected in August 2019. If compelling clinical data are generated demonstrating the benefits of the combined treatment, we believe the data from this Phase 2 clinical trial could support a filing with regulatory authorities for marketing approval.

We are also developing additional product candidates, RP2 and RP3, built on our Immulytic platform, that are further engineered to enhance anti-tumor immune responses and intended to address additional tumor types. RP2 has been engineered to express an antibody-like molecule that blocks the activity of CTLA-4, a protein that inhibits the immune response to tumors. RP3 is engineered with the intent of not only blocking the activity of CTLA-4, but also to further stimulate an anti-tumor response through activation of the immune co-stimulatory pathways through expression of the ligands for CD40 and 4-1BB.

We intend to initiate a Phase 1 clinical trial with RP2 alone and in combination with nivolumab in the third quarter of 2019, pending our response to queries from the FDA in the United States and the Medicines and Healthcare products Regulatory Agency, or MHRA, in the United Kingdom regarding certain Chemistry, Manufacturing, and Controls, or CMC aspects of the clinical trial. These queries, which we received from the FDA and MHRA in February 2019 and May 2019, respectively, were in response to our submission of pre-IND questions to the FDA and the CTA, respectively. Our responses to these queries, including with respect to the FDA, the development of a further analytical data, have delayed the intended opening of this Phase 1 clinical trial beyond the second quarter of 2019 as we originally intended. The clinical trial is now expected to initiate, initially in the UK, in the third quarter of 2019. The Phase 1 clinical trial of RP2 will also be conducted as a collaboration with BMS, under which it has granted us a non-exclusive, royalty-free license to, and will supply at no cost, nivolumab, for use in combination with RP2. BMS has no further development-related obligations under this collaboration.

We intend to file an IND and/or foreign equivalents for RP3 and, assuming regulatory clearance, enter clinical development during 2020. IND enabling studies are currently underway.

Our product candidates are administered by direct injection into solid tumors, guided either visually or by ultrasound or other imaging methods. We believe that direct injection maximizes virus-mediated tumor cell death, provides the most efficient delivery of virus-encoded immune activating proteins into the tumor with the goal of activating systemic immunity, and limits the systemic toxicities that could be associated with intravenous administration. Activation of systemic immunity through local administration can lead to the induction of tumor responses in tumors which have not themselves been injected, which is known as an "abscopal" effect.

Our strategy

Our goal is to create the leading oncolytic immunotherapy company that discovers, develops and commercializes next-generation products with multiple mechanisms of action for the treatment of a broad range of solid tumor types. Key elements of our strategy include the following:

Advance the development of, and seek regulatory approval for, our lead product candidate, RP1. We are advancing two clinical trials for RP1. We are currently initiating a randomized, controlled Phase 2 clinical trial of RP1 in combination with cemiplimab, versus cemiplimab alone, in approximately 240 patients with CSCC, which we have designed to potentially support product registration. In addition, we are currently conducting the Phase 2 part of our Phase 1/2 clinical trial of RP1 in combination with nivolumab, enrollment of which is currently open for three of the four intended tumor type cohorts. We then intend to analyze each cohort's data to determine the indications that merit further clinical development.

Initiate the clinical development of and obtain regulatory approval for RP2, our next product candidate. We have engineered RP2, which is based on RP1 but additionally expresses an anti-CTLA-4 antibody-like protein, to target tumor types that do not respond to single-agent immune checkpoint blockade therapies and patients who have not responded to or who have progressed on anti-PD-1/L1 therapy. In the third quarter of 2019, we plan to initiate a Phase 1 clinical trial of RP2 alone and in combination with nivolumab following receipt of regulatory approval to proceed in the United States and/or United Kingdom. Pending the results of this Phase 1 clinical trial, we intend to initiate separate Phase 2 clinical trials in individual tumor types, currently intended to include triple negative breast cancer and two additional indications, which we expect to define in the second half of 2019.

Leverage our Immulytic platform to build a portfolio of product candidates that target a range of immune mechanisms and progress these product candidates into the clinic. We plan to utilize our Immulytic platform to develop additional product that express further combinations of proteins aimed at activating multiple immune mechanisms for the treatment of a broad range of solid tumor types. Our intended goal in the coming years is to introduce one product candidate into the clinic each year. Current focus, however, is on the development of RP1, RP2 and RP3 rather than expansion of the pipeline beyond these product candidates.

Apply our extensive expertise to establish, equip, and operate our own in-house manufacturing facility. We intend to establish, equip, and operate our own manufacturing facility in Framingham, Massachusetts for multi-product current Good Manufacturing Practice, or cGMP, manufacturing. We expect our facility to be ready to produce clinical-grade material during the first half of 2020 and ultimately to be able to support commercial product launch.

Retain significant economic and commercial rights to our product candidates in key geographic areas. We intend to retain rights in the United States for our product candidates and to develop an oncology-focused commercial organization. When economically attractive, we intend to evaluate and enter into development and marketing agreements with pharmaceutical and biotechnology partners for geographic areas in which we are unlikely to pursue development and commercialization on our own.

Immuno-oncology background and limitations of existing therapies

Cancer is a broad group of diseases in which normal cells are transformed into a state of rapid and uncontrolled cell division, typically forming tumors. Cancer originates from a particular tissue in the body, such as the lung or skin, and often spreads, or metastasizes, as the disease progresses. Tumors are comprised of multiple cell types, including cancerous cells and immune cells. The composition and the type of tumor dictate the aggressiveness of a particular cancer, its susceptibility to treatment, and ultimately the outcome for the patient. A promising new approach to cancer treatment, which is the

subject of significant ongoing drug development activity, is to activate the immune system against cancer.

The immune system contains many different cell types that fall into two general categories, cells of the innate immune system and cells of the adaptive immune system. The innate immune system is a first-line, ubiquitous, non-specific defense mechanism aimed at combating elements that the body views as foreign, particularly microbial pathogens and parasites, but also tumor cells. After the innate immune system is activated, an adaptive immune response is triggered that is specific to particular proteins, known as antigens. The adaptive immune system is flexible and can evolve. Importantly, it has the capacity for immune memory, or the ability to be recalled into action if the same foreign antigen is detected in the body in the future. Activation of both the innate and adaptive components of the immune system is believed to be essential for the induction of an effective anti-cancer immune response.

Immune checkpoints are key mechanisms of the adaptive immune system that function to inhibit immune responses and, in particular, to prevent the induction of autoimmunity. In the cancer setting, tumors can hijack these immune checkpoints such that the tumors become protected from the effects of anti-cancer immunity. This enables tumors to continue growing without or with reduced immune interference, even if an anti-tumor immune response had been initiated. Additional immune checkpoints inhibit the initial induction of an immune response, rather than subsequently protecting the tumor from a previously established immune response.

Checkpoint inhibitor therapies block these negative regulators of the immune system with the intent of either rendering tumors susceptible to immune attack and/or increasing the potency of the anti-tumor immune response that is generated. This approach to cancer therapy has the potential to result in long-lasting anti-cancer effects in certain patients with certain tumor types. To date, multiple immune checkpoint blockade products have been approved in a number of cancer indications, and there are numerous other related drug candidates in preclinical and clinical development. Market researchers forecast that immuno-oncology treatments will grow to over $25 billion a year in sales globally by 2022.

While immune checkpoint blockade has been a transformational treatment for many patients with cancer, the majority of patients do not respond to current treatments. This is because checkpoint blockade therapies require a pre-existing immune response to a patient's tumor and that the tumors be "inflamed," or "hot." Because many patients do not have an ongoing pre-existing anti-tumor immune response, which is often referred to as a tumor being immunologically "cold," only a minority of patients respond to checkpoint blockade therapies alone. We therefore believe that the ability to effectively convert "cold" tumors to "hot" would substantially increase the response rates and the types of tumors which are susceptible to immune checkpoint blockade therapies.

Our approach—Oncolytic immunotherapy

Our product candidates are designed to induce a robust immune response against a patient's cancer and turn immunologically "cold" tumors "hot." To achieve this objective, we use oncolytic immunotherapies that combine multiple mechanisms of action in a single product candidate. We believe our product candidates will initiate or enhance an immune response in patients with no or minimal pre-existing cancer immunity, including to tumor neo-antigens, and thereby increase the effectiveness of immune checkpoint blockade therapies.

Oncolytic immunotherapy is the treatment of cancer with viruses that selectively replicate in tumors as compared to normal tissue, thereby killing the virus-infected tumor cells. In addition to this direct oncolytic killing of cancer cells, the presence of the virus and the generation of immune-stimulating tumor cell death triggers both innate and adaptive immune responses that result in further tumor destruction, intended to result in the establishment of lasting anti-tumor immunity.

Our product candidates are intended to act at several key points in the pathways involved in the initiation of an immune response. Following direct injection into tumors, our viruses replicate in cancer cells and then lyse, or break them open, releasing tumor antigens, including neo-antigens specific to the patient, which could otherwise be hidden from the immune system. This process of necrotic cell death releases intra-cellular markers of "danger," the danger associated molecular patterns, or DAMPs, while the virus produces pathogen associated markers of danger, or PAMPs. These trigger various pathways of the innate immune system, including the STING pathway and pathways mediated through toll-like receptors, or TLRs, each resulting in the production of interferon. Innate immune activation would be expected to itself provide anti-tumor effects, as interferon activates natural killer cells which can destroy tumor cells. Innate immune activation would also be expected to help to trigger adaptive anti-cancer immunity, in which antigen presenting cells, or APCs, are attracted to the injected tumor. APCs internalize cancer antigens, including neo-antigens, and traffic back to the draining lymph nodes where they present the antigens to T cells. These are then primed to proliferate and disperse systemically to seek and destroy cancer cells with the same antigen profile throughout the body with the aim of destroying distant tumor deposits.

To further augment these intended effects, our oncolytic immunotherapies are intended to genetically encode and express multiple potent cell-killing and immune-stimulating proteins in the tumor—in other words, our oncolytic immunotherapies are "armed" with these therapeutic genes.

We believe that our ability to incorporate multiple mechanisms of action into a practical "off-the-shelf" approach to initiating or enhancing an anti-tumor immune response, including to neo-antigens, will offer significant advantages over the various approaches to immune activation that are currently in development, including personalized vaccine treatments. Tumor neo-antigens are uniquely present in tumors as compared to normal tissue because they result from the genetic changes that occur as cancer develops. Unlike the antigens present in normal tissue, the immune system sees neo-antigens as foreign. As a result, the immune system is able to mount an immune response to tumor neo-antigens in the same way that it would to the antigens contained in disease-causing micro-organisms, which the immune system also sees as foreign. Researchers believe immune responses to tumor neo-antigens are particularly important in providing the patient's immune system the ability to combat cancer, and as a consequence various "personalized vaccine" approaches to generating immune responses to tumor neo-antigens are in development. These approaches are generally both expensive and time consuming because a vaccine cannot be designed and manufactured until a tumor biopsy is taken and analyzed in the laboratory to identify the mutated tumor antigens that will be targeted by the treatment. We believe that our approach may also offer significant advantages over other approaches to anti-cancer immune activation that only target a single pathway of the immune system, as is the case with most of the other immuno-oncology therapies currently under development. Importantly, our product candidates are intended to maximally activate an immune response against cancer, the missing element needed to allow anti-PD-1 or anti-PD-L1 therapy to treat more patients and tumor types, unlike some other therapies which are intended to act by blocking additional defense mechanisms against an anti-tumor immune response once it has been initiated.

Our Immulytic platform

The foundation of our oncolytic immunotherapy product candidates, which we call our Immulytic platform, consists of a proprietary strain of HSV-1 that we have engineered to replicate selectively in tumors and to express a fusogenic glycoprotein, a protein that triggers the fusion of the membranes between cells. HSV-1 is both highly cell lytic and inflammatory, and also has a large carrying capacity, which makes it possible to incorporate multiple genes encoding therapeutic proteins. We believe our combination of HSV-1 with the expression of the fusogenic glycoprotein increases the natural ability of HSV-1 to kill tumor cells and to induce an anti-tumor immune response. The fusogenic functionality of our product candidates is intended not only to increase the number of tumor cells that are killed, but

also to cause highly immunogenic death of tumor cells. We believe that these factors will increase the potency of the systemic anti-tumor immune response that is generated by our product candidates. With the intention of amplifying the anti-tumor response further, we have also engineered our product candidates to express in tumors a range of additional, potent, immune activating genes encoding therapeutic proteins. Our lead product candidate, RP1, serves as the base for the development of these additional oncolytic immunotherapies expressing further therapeutic proteins. In addition to RP1, our current pipeline products are RP2 and RP3.

We believe that our intended step-wise development approach from RP1 through RP3 reduces clinical risk, as we will be able to study the safety profile of each therapeutic protein prior to moving to the next product candidate with an additional therapeutic protein that is intended to provide more potent anti-tumor immune effects.

Lead product candidate: RP1

Our lead product candidate, RP1, is a selectively replicating version of HSV-1 that expresses GALV-GP R(-) and human GM-CSF. RP1 has the following properties:

- We have deleted the ICP34.5-encoding gene, which enables tumor-selective virus replication;
- We have deleted the ICP47-encoding gene, which is intended to prevent the inhibition of the antigen presentation pathway otherwise caused by ICP47 binding to the transporter associated with antigen presentation. ICP47 deletion is also intended to result in the increased and earlier expression of the HSV-1 US11 gene by placing the HSV-1 US11 gene under the control of ICP47 promoter. This increases virus replication in tumors without reducing tumor-selectivity; and
- We have inserted the sequences for GALV-GP R(-) and human GM-CSF, which results in the expression of these therapeutic proteins with the intention of increasing both the direct tumor cell killing and the potency of the anti-tumor immune response that is induced.

We are developing RP1 for use in combination with immune checkpoint blockade therapy, particularly therapies targeting PD-1 or PD-L1. We believe that the robust release of tumor antigens and the highly immunogenic tumor cell death intended to be caused by RP1 will further increase the synergy previously seen between oncolytic viruses and immune checkpoint blockade therapy.

Preclinical results

In one of our preclinical experiments, tumors were induced in both the left and right flanks of rats. RP1 was then injected into the tumors in only the right flanks. We observed destruction not only of the injected tumors in the right flanks, but also of the large un-injected tumors in the left flanks of 70% of the treated rats. When formulation buffer with no RP1 was injected into "control" rats, no impact on the growth of the injected or un-injected tumors was observed. This effect of RP1 in both injected and un-injected tumors provides support for the potent systemic, or "abscopal," effect of RP1.

Phase 1/2 clinical trial in multiple tumor types

We are currently conducting a Phase 1/2 clinical trial with RP1 in approximately 150 patients. We have completed enrollment of the Phase 1 dose rising part of this clinical trial in which we are assessing the safety and tolerability of RP1 administered alone in 22 patients with mixed advanced solid tumor types and, following the review of the data by the SRC, have determined the dose regimen to be administered in the Phase 2 part of this clinical trial. We are completing enrollment of a Phase 1 expansion cohort of approximately 12 patients in which we are assessing the safety and efficacy of RP1 administered in combination with nivolumab. One patient with MSI-H/dMMR remains to be enrolled in the expansion cohort. We have designed the Phase 1 part of the trial to provide insights on the

effects of RP1 on tumors, including necrosis, inflammation and erythema, the biodistribution of RP1 in the blood, saliva and mucosa, and the impact of RP1 administration on anti-HSV-1 antibody responses. For the patients in the Phase 1 part of the trial who also receive nivolumab, we are assessing certain biomarkers indicative of immune activation in tumor biopsies. These include the infiltration of T cells, expression of PD-L1, and the presence of an "inflamed gene signature," each of which would indicate ongoing immune activation.

The Phase 2 part of this clinical trial is designed to assess the safety and efficacy of RP1 in combination with an anti-PD1 therapy in four cohorts of approximately 30 patients with melanoma, non-melanoma skin cancers, bladder cancer and MSI-H/dMMR. Following SRC review of the Phase 1 data to date, we have opened enrollment in the United States and the United Kingdom of the melanoma, bladder cancer, and non-melanoma skin cancer Phase 2 cohorts, and will open enrollment of the MSI-H-dMMR Phase 2 cohort after a final evaluable MSI-H/dMMR patient has been enrolled in the Phase 1 expansion cohort without safety concerns. In the Phase 2 part of the clinical trial, we are also evaluating efficacy under the clinical trial protocol, primarily on the basis of the proportion of patients who have a response within each tumor type cohort. Responses are either defined as a partial response (a 30% or greater reduction in tumor size) or a complete response (a complete eradication of the disease). We then intend to analyze each cohort's data to determine the indications that merit progressing into further clinical development. We have chosen the tumor types in the Phase 2 part of the clinical trial because they have shown that they have some level of underlying responsiveness to treatment with immune checkpoint blockade therapies but for which we believe considerable unmet medical need remains. We intend to expand the number of patients treated and/or add a control arm for each cohort where we see promising signs of efficacy, either as part of the same clinical trial or as separate clinical trials, as a means to gather more definitive data in support of the clinical benefit of the combination of RP1 and nivolumab in these respective tumor types. We believe that the expanded clinical trials can be designed to support a filing with regulatory authorities for marketing approval.

This Phase 1/2 clinical trial is being conducted as a collaboration with Bristol-Myers Squibb Company, or BMS, under which it has granted us a non-exclusive, royalty-free license to, and is supplying at no cost, its anti-PD-1 therapy, nivolumab, for use in combination with RP1 in this clinical trial. BMS has no further development-related obligations under this collaboration.

Phase 2 clinical trial in CSCC

We are also planning to initiate a randomized, controlled Phase 2 clinical trial of RP1 in combination with cemiplimab, versus cemiplimab alone, in approximately 240 patients with cutaneous squamous cell carcinoma, or CSCC. Initial study site activation is currently underway in the United States and Australia, with study initiation expected in August 2019. This clinical trial will be conducted in collaboration with Regeneron. If compelling clinical data are generated demonstrating the benefits of the combined treatment, we believe the data from this trial could support a filing with regulatory authorities for marketing approval.

Product candidate pipeline

We are also developing additional product candidates, RP2 and RP3, built on our Immulytic platform, that are further engineered to enhance anti-tumor immune responses and intended to address additional tumor types. RP2 has been engineered to express an antibody-like molecule that blocks the activity of CTLA-4, a protein that inhibits the immune response to tumors. RP3 is engineered with the intent of not only blocking the activity of CTLA-4, but also to further stimulate an anti-tumor response through activation of the immune co-stimulatory pathways through expression of the ligands for CD40 and 4-1BB.

Pipeline product candidate: RP2

We have designed our RP2 product candidate to express an anti-CTLA-4 antibody-like protein in order to block the inhibition of the immune response otherwise caused by CTLA-4. We believe that RP2 will offer advantages compared with current CTLA-4 approaches, including ipilimumab. By expressing anti-CTLA-4 only locally in the tumor and draining lymph nodes, we believe that activity will be retained, but that toxicity will be reduced. We intend that our RP2 product candidate will be used in combination with anti-PD-1 therapy, which we believe will result in both synergy with the oncolytic virus and the expression of the anti-CTLA-4 in the tumor.

We intend to administer RP2 in combination with anti-PD-1 or anti-PD-L1 therapy in tumor types with poor responsiveness to anti-PD-1/L1 therapy alone, and in patients who have not responded to or who have progressed on prior anti-PD-1/L1 therapy. We currently expect to include patients with triple negative breast cancer and two further indications in our initial clinical trial with RP2, and we expect to determine which tumor types to target in the second half of 2019.

Preclinical results

We have conducted preclinical tests comparing RP1 and RP2 to determine the effect of expressing the anti-CTLA-4 antibody-like protein and have observed an enhanced effect with RP2. In one of these preclinical experiments, tumors were induced in both the left and right flanks of mice. Either RP1 or RP2 was then injected into the tumors in only the right flanks. We observed enhanced destruction of tumors with RP2 as compared to RP1, particularly of the un-injected tumors. In this experiment only a low dose of virus was used such that with RP1 un-injected tumors only partially responded to the treatment. This was to allow the potential benefits of anti-CTLA-4 expression to be observed.

In a further experiment with RP2 in combination with anti-PD-1 therapy, we demonstrated that the responses in 15 mice in which tumors had been eradicated were durable and that all but one of these mice were protected against re-challenge with tumor cells, demonstrating that memory immune responses had been induced.

Planned Phase 1 clinical trial

We intend to initiate a Phase 1 clinical trial with RP2 alone and in combination with nivolumab in the third quarter of 2019, pending our response to queries from the FDA in the United States and the MHRA in the United Kingdom regarding certain CMC aspects of this Phase 1 clinical trial with RP2, as described below. Our responses to these queries have delayed the intended opening of this Phase 1 clinical trial with RP2 beyond the second quarter of 2019 as we originally intended. This Phase 1 clinical trial of RP2 will also be conducted as a collaboration with BMS, under which it has granted us a non-exclusive, royalty-free license to, and will supply at no cost, nivolumab, for use in combination with. BMS has no further development-related obligations under this collaboration.

Regulatory status

In the United Kingdom, prior to filing a CTA, we participated in a pre-CTA meeting with the MHRA in December 2018. We subsequently filed our CTA with the MHRA in February 2019 and received a response with a number of queries in March 2019. We responded to the MHRA in April 2019 and in May 2019 the MHRA notified us that further CMC information was required. In June 2019, the MHRA provided clarification with respect to the required information, which related to the provision of additional comparability data between the intended clinical batches and those used in non-clinical studies. We expect that, after submitting the requested data to the MHRA, we will initiate the Phase 1 clinical trial with RP2 alone and in combination with nivolumab in the third quarter of 2019, rather than the second quarter as originally planned.

In the United States, we submitted pre-IND questions to the FDA in January 2019 and the FDA responded in February 2019 with a number of CMC related queries, including indicating the need for further analytical data to be generated and that further justification was required for certain aspects of the intended clinical trial protocol. We are currently addressing these queries and expect to file an IND with the FDA once they have been addressed.

Pipeline product candidate: RP3

We have designed our RP3 product candidate to express immune-activating proteins that stimulate T cells, in addition to anti-CTLA-4 and GALV-GP R(-). These immune activating proteins are the ligands for two immune co-stimulatory pathways responsible for T cell proliferation and/or activation, the CD40 and 4-1BB pathways. Pre-clinical studies with RP3 are currently underway, with Good Laboratory Practice, or GLP, toxicology and biodistribution studies expected in the second half of 2019. As with RP2, we intend to study RP3 in indications that are less responsive to anti-PD-1 or anti-PD-L1 therapy. We expect to bring RP3 into clinical development in 2020.

Preclinical results

We have conducted preclinical tests to assess the benefit of expressing immune co-stimulatory pathway ligands, and have observed an enhanced effect associated with the expression of these proteins as compared to RP1. In one of these preclinical experiments, tumors were induced in both the left and right flanks of mice. Either RP1 or versions of RP1 additionally expressing the ligands which activate CD40, 4-1BB or OX40 were then injected into the tumors in only the right flanks. We observed enhanced destruction of tumors with the co-stimulatory pathway ligand expressing viruses as compared to RP1, particularly of the un-injected tumors. In this experiment only a low dose of virus was used such that with RP1 un-injected tumors only partially responded to the treatment. This was to allow the potential benefits of co-stimulatory pathway ligand expression to be observed. After evaluation of our own data relating to the activity of immune co-stimulatory pathway activating ligands, as well as external clinical data targeting these pathways, we chose to incorporate CD40 ligand and 4-1BB ligand into RP3

Intellectual property

We believe our rights under issued patents, if obtained, and patent applications will provide a competitive advantage. Our success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing upon our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing United States and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary position.

For the core technology in our Immulytic platform and each of our product candidates, we have filed five patent applications under the Patent Cooperation Treaty, or PCT, and four U.S. provisional applications. Four of these PCT applications have entered the national phase and are pending in a range of countries, and one is still in the international phase. None of our PCT-derived patent applications or U.S. provisional applications have been granted by a patent office. Early stage examination has started only in connection with the European national phase applications.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, the patent term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits

patent term restoration of a portion of the patent term lost during the U.S. clinical development and FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under clinical development in the United States and the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, and if and when patents grant, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any of our issued patents in any jurisdiction where these are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

We may rely, in some circumstances, on trade secrets to protect our technology. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, scientific advisors and other contractors, as well as physical security of our premises and our information technology systems.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary rights. We compete in the highly competitive markets that address cancer and face significant competition from many sources, including pharmaceutical, biopharmaceutical and biotechnology companies, as well as universities and private and public research institutions. Many of our competitors have significantly greater financial, manufacturing, marketing and drug development resources than we do. Large biopharmaceutical companies in particular have extensive experience in clinical testing and in obtaining regulatory approvals for drugs and biologicals. These companies also have significantly greater research capabilities than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies or universities and research institutions.

Our competitors fall primarily into the following groups of treatment:

- traditional cancer therapies, including chemotherapy, surgery, radiation and targeted therapies;
- approved immunotherapy antibodies and immunotherapy antibodies in clinical trials;
- oncolytic immunotherapies, including T-Vec and other oncolytic immunotherapies in clinical trials;
- therapies aimed at activating innate immunity such as those targeting STING and TLRs;
- cancer vaccines including personalized vaccines and those targeting tumor neo-antigens; and
- cell-based therapies, such as CAR-T, T cell receptor-based, and NK cell therapies.

Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects, are easier to administer or are less expensive alone or in combination with other therapies than any products that we may develop alone or in combination with other therapies, especially if these get to market sooner than our products. These third parties also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

Our oncolytic product candidates, if and when marketed, will compete with a number of drugs that are currently marketed or in development that also target cancer but that utilize a different mechanism of action. To compete effectively with these agents, our product candidates will need to demonstrate advantages that lead to improved clinical efficacy and safety compared with these competitors. At the same time, however, we believe that our oncolytic product candidates, if and when ultimately marketed, would likely be used principally in combination with checkpoint blockade therapies in addition to existing cancer therapies, including surgery, chemotherapy, radiation therapy and other biological therapies such as antibodies targeting particular surface receptors. We therefore believe that our product candidates, if and when marketed, would largely complement rather than compete directly with these existing treatment options.

We do, however, expect to face direct and increasing competition from a number of companies that are also seeking to develop cancer therapies based on oncolytic viruses and other ways to prime the immune system, including neo-antigen vaccination. We believe that our ability to successfully compete will depend, among other things, on our ability to:

- expeditiously advance the development of our product candidates;
- design, enroll patients in and successfully complete appropriate clinical trials in a timely fashion;
- gain regulatory approval for our product candidates in their first indications as well as further indications;
- establish collaborations and partnerships for the development and marketing of our product candidates;
- commercialize our product candidates successfully, including convincing physicians, insurers and third-party payors of the safety and efficacy of our product candidates over currently approved therapies;
- secure and protect intellectual property rights based on our innovations; and
- manufacture or otherwise obtain and sell commercial quantities of future products to the market.

Manufacturing and suppliers

We have established an operations leadership team with extensive experience in manufacturing biologics based on viruses, including oncolytic products and gene therapy products, and in the construction, validation, approval and operation of facilities designed to manufacture biologics. Our team has already developed a robust and reproducible manufacturing process for our product candidates. We are also developing our product candidates for maximum practicality of use compared with some other oncolytic immunotherapies; in particular, our product candidates do not require refrigeration at -70^0 Celsius at clinical sites.

To date, our third-party contract manufacturer in Europe has been responsible for sourcing raw materials for use in the manufacture, in accordance with cGMP, of our product candidates for use in our planned early clinical trials. We currently use fetal bovine sera, a commonly used growth supplement, in the initial growth of the mammalian cells used in the production of our viral product candidates and a recombinant human protein to increase the stability of our drug formulation. We are in the process of developing our raw material supply chain for our product candidates as part of the process of establishing our own manufacturing facility and intend to enter into commercial supply, collaboration or similar agreements prior to conducting advanced clinical trials.

We have leased an approximately 63,000 square-foot facility in Framingham, Massachusetts, where we plan to operate our own in-house manufacturing facility in order to secure supplies for pivotal

studies and commercial launch. Construction is underway and planned to be substantially complete by the end of 2019. This facility is intended to give us control over key aspects of the supply chain for our products and product candidates. We are designing this facility to allow us to produce two different products in parallel and several different products in the same facility.

By establishing our own manufacturing facility, we aim to minimize or eliminate our reliance on contract manufacturing organizations, which typically have limited capacity at commercial scale and quality. We believe that having control over the whole manufacturing process will allow us to reduce cycle times and cost of goods for commercial production and to shorten overall timelines for new product candidates in our development pipeline, as well as help us to develop drug formulations or presentations to simplify distribution and/or administration of future oncolytic immunotherapies. We also believe that having a dedicated manufacturing facility will allow us to optimize commercial-scale processes and to develop a suitable workforce capable of supporting market launch.

Sales and marketing

None of our product candidates has been approved for sale. If and when our product candidates receive marketing approval, we intend to commercialize them on our own in the United States and potentially with pharmaceutical or biotechnology partners in other geographies. We currently have no sales, marketing or commercialization capabilities and have no experience as a company doing such activities. However, we intend to build the necessary capabilities and infrastructure over time following the advancement of our product candidates. Clinical data, the size of the opportunity and the size of the commercial infrastructure required will influence our commercialization plans and decision making.

Collaborations

BMS

On February 26, 2018, we entered into a Clinical Trial Collaboration and Supply Agreement with BMS. Pursuant to the agreement, BMS will provide to us, at no cost, nivolumab, its anti-PD-1 therapy, for use in combination with RP1 in our ongoing Phase 1/2 clinical trial. Under the agreement, we will sponsor, fund and conduct the clinical trial in accordance with an agreed-upon protocol. Under the agreement, BMS has granted us a non-exclusive, non-transferrable, royalty-free license (with a right to sublicense) under its intellectual property to use nivolumab in the clinical trial and has agreed to supply nivolumab, at its cost and for no charge to us, for use in the clinical trial. Both parties will own the study data produced in the clinical trial, other than study data related solely to nivolumab, which will belong solely to BMS, or study data related solely to RP1, which will belong solely to us.

Unless earlier terminated, the agreement will remain in effect until (a) the completion of the clinical trial, (b) all related clinical trial data have been delivered to both parties and (c) the completion of any statistical analyses and bioanalyses contemplated by the clinical trial protocol or any analysis otherwise agreed upon by the parties. The agreement may be terminated by either party (i) in the event of an uncured material breach by the other party, (ii) in the event the other party is insolvent or in bankruptcy proceedings or (iii) for safety reasons. Upon termination, the licenses granted to us to use nivolumab in the clinical trial will terminate. The agreement contains representations, warranties, undertakings and indemnities customary for a transaction of this nature.

Regeneron

On May 29, 2018, we entered into a Master Clinical Trial Collaboration and Supply Agreement with Regeneron. Pursuant to the agreement, we agreed to undertake one or more clinical trials with Regeneron for the administration of our product candidates in combination with cemiplimab, an anti-PD-1 therapy developed by Regeneron, across multiple solid tumor types, the first of which is intended to be our planned Phase 2 clinical trial of RP1 in patients with CSCC. Each clinical trial will be conducted pursuant to an agreed study plan which, among other things, will identify the name of the sponsor and which party will manage the particular study, and include the protocol, the budget and a schedule of clinical obligations. The first study plan related to the Phase 2 clinical trial has been agreed.

Pursuant to the terms of the agreement, each party granted the other party a non-exclusive license of their respective intellectual property and agreed to contribute the necessary resources to fulfill their respective obligations, in each case, under the terms of the agreed study plans. Development costs of a particular clinical trial will be split equally. The agreement contains certain covenants that restrict us from entering into a third-party arrangement with respect to the use of our product candidates in combination with an anti-PD-1 therapy and that restrict Regeneron from entering into a third-party arrangement with respect to the use of cemiplimab in combination with an HSV-1 based product, in each case, for the treatment of a tumor type that is the subject of a clinical trial to which the covenants apply. Unless otherwise mutually agreed in a future study plan, these covenants are only applicable to our planned Phase 2 clinical trial in CSCC and expire upon the one-year anniversary of the commencement of the applicable study plan.

The agreement may be terminated by either party if (i) there is no active study plan for which a final study report has not been completed, (ii) the parties have not entered into a study plan for an additional clinical trial within a period of time after the delivery of the most recent final study report or (iii) in the event of a material breach. The agreement contains representations, warranties, undertakings and indemnities customary for a transaction of this nature.

Regulatory matters

Government authorities in the United States, at the federal, state, and local level, and in other countries, extensively regulate, among other things, the research, development, testing, approval, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import, and export of biopharmaceutical products such as those we are developing. In addition, manufacturers of biopharmaceutical products participating in Medicaid and Medicare are required to comply with mandatory price reporting, discount, and rebate requirements. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

FDA and EU regulation

In the United States, the FDA regulates biologics under the Federal Food, Drug, and Cosmetic Act, or FDCA, the Public Health Services Act, or PHSA, and their implementing regulations. The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies, and formulation studies in compliance with GLP regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin at United States clinical trial sites;

- approval by an IRB for each clinical site, or centrally, before each trial may be initiated;
- adequate and well-controlled human clinical trials to establish the safety, purity, and potency of the proposed product candidate for its intended use, performed in accordance with GCPs;
- development of manufacturing processes to ensure the product candidate's identity, strength, quality, purity, and potency;
- submission to the FDA of a BLA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the products are produced to assess compliance with current cGMPs, and to assure that the facilities, methods, and controls are adequate to preserve the therapeutics' identity, strength, quality, purity, and potency as well as satisfactory completion of an FDA inspection of selected clinical sites and selected clinical investigators to determine GCP compliance; and
- FDA review and approval of the BLA to permit commercial marketing for particular indications for use.

Preclinical studies and IND submission

The testing and approval process of product candidates requires substantial time, effort, and financial resources. Satisfaction of the FDA's pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease. Preclinical studies include laboratory evaluation of chemistry, pharmacology, toxicity, and product formulation, as well as animal studies to assess potential safety and efficacy. Such studies must generally be conducted in accordance with the FDA's GLPs. Prior to commencing the first clinical trial at a United States investigational site with a product candidate, an IND sponsor must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data, any available clinical data or literature, and proposed clinical study protocols among other things, to the FDA as part of an IND.

An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, notifies the applicant of safety concerns or questions related to one or more proposed clinical trials and places the trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during trials due to safety concerns or non-compliance. As a result, submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development.

Clinical trials

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with federal regulations and GCP requirements, which include the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial, as well as review and approval of the study by an IRB. Investigators must also provide certain information to the clinical trial sponsors to allow the sponsors to make certain financial disclosures to the FDA. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the trial procedures, the parameters to be used in monitoring safety, the effectiveness criteria to be evaluated, and a statistical analysis plan. A protocol for each clinical trial, and any subsequent protocol amendments, must be submitted to the FDA as part of the IND. In addition, an IRB at each study site participating in the clinical trial or a central IRB

must review and approve the plan for any clinical trial, informed consent forms, and communications to study subjects before a study commences at that site. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits, and whether the planned human subject protections are adequate. The IRB must continue to oversee the clinical trial while it is being conducted. Once an IND is in effect, each new clinical protocol and any amendments to the protocol must be added to the IND for FDA review, and to the IRB for approval. If a product candidate is being investigated for multiple intended indications, separate INDs may also be required. Progress reports detailing the results of the clinical trials must also be submitted at least annually to the FDA and the IRB and more frequently if serious adverse events or other significant safety information is found.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or if the trial poses an unexpected serious harm to subjects. The FDA or an IRB may also impose conditions on the conduct of a clinical trial. Clinical trial sponsors may also choose to discontinue clinical trials as a result of risks to subjects, a lack of favorable results, or changing business priorities.

Information about certain clinical trials, including a description of the study and study results, must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their clinicaltrials.gov website. Manufacturers or distributors of investigational products for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions must also have a publicly available policy on evaluating and responding to requests for expanded access requests.

Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial that regularly reviews accumulated data and advises the study sponsor regarding the continuing safety of the trial. This group may also review interim data to assess the continuing validity and scientific merit of the clinical trial. This group receives special access to unblinded data during the clinical trial and may advise the sponsor to halt the clinical trial if it determined there is an unacceptable safety risk for subjects or on other grounds, such as no demonstration of efficacy.

The manufacture of investigational biologics for the conduct of human clinical trials is subject to current cGMP requirements. Investigational biologics and active ingredients imported into the United States are also subject to regulation by the FDA. Further, the export of investigational products outside of the United States is subject to regulatory requirements of the receiving country as well as United States export requirements under the FDCA.

In general, for purposes of BLA approval, human clinical trials are typically conducted in three sequential phases, which may overlap or be combined.

- Phase 1—Trials are initially conducted in healthy human volunteers or subjects with the target disease or condition and test the product candidate for safety, dosage tolerance, structure-activity relationships, mechanism of action, absorption, metabolism, distribution, and excretion. If possible, Phase 1 trials may also be used to gain an initial indication of product effectiveness.

- Phase 2—Controlled trials are conducted in limited subject populations with a specified disease or condition to evaluate the effectiveness of the product candidate for a particular indication or indications, identify optimal dosages, dosage tolerance and schedule, possible adverse effects and safety risks, and expanded evidence of safety.

- Phase 3—These adequate and well-controlled clinical trials are undertaken in expanded subject populations, generally at geographically dispersed clinical trial sites, to generate enough data to provide statistically significant evidence of clinical efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product. Typically, two Phase 3 trials are required by the FDA for product approval. Under some limited circumstances, however, the FDA may approve a BLA based upon a single Phase 3 clinical trials.

Additional kinds of data may also help to support a BLA, such as patient experience data.

Further, under certain circumstances, manufacturers and sponsors of investigational biopharmaceutical product candidates can provide access to the product candidates to certain qualifying patients outside of clinical trials. For instance, under the FDA's expanded access program, with FDA approval and subject to certain requirements, sponsors may provide access to product candidates to patients with serious or immediately life threatening diseases or conditions for which there is no comparable or satisfactory alternative therapy, provided that the potential patient benefit justifies the risks, the risks are not unreasonable in the context of the disease or condition to be treated, and the provision of the product candidate for the requested use will not interfere with clinical investigations. The specific expanded access criteria and requirements depend on the number of expanded access patients. Sponsors and investigators of expanded access programs must still comply with the FDA's clinical trial guidelines and are subject to protection regulations. Federal and state laws in the United States, referred to as right to try laws, also establish a separate mechanism through which certain patients with life threatening diseases or conditions, who have exhausted all approved treatment options and are unable to participate in a clinical trial, may request access to investigational product candidates that have completed a Phase 1 clinical trial. While certain criteria must be met for a patient to be eligible for access to product candidates under right to try laws, these laws do not require the FDA to approve the use of the product candidate and do not require compliance with the majority of the FDA's clinical trial regulations.

The FDA may also require, or companies may conduct, additional clinical trials for the same indication after a product is approved. These so-called Phase 4 trials may be made a condition to be satisfied after approval. The results of Phase 4 trials can confirm or refute the effectiveness of a product candidate and can provide important safety information.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with current cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, manufacturers must develop methods for testing the identity, strength, quality, potency, and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

In relation to the clinical trial in the United Kingdom and in so far as trials will be conducted in other countries with a view to obtaining a marketing authorization from the European Medicines Agency, there are equivalent cGMP requirements and European Union regulatory rules that are implemented nationally. However, enforcement of such rules is conducted by the regulatory authority in which the trial is carried out, which is the MHRA in the United Kingdom.

BLA submission, review by the FDA, and marketing approval

Assuming successful completion of the required clinical and preclinical testing, the results of product development, including chemistry, manufacture, and controls, non-clinical studies, and clinical

trial results, including negative or ambiguous results as well as positive findings, are all submitted to the FDA, along with the proposed labeling, as part of a BLA requesting approval to market the product for one or more indications. In most cases, the submission of a BLA is subject to a substantial application user fee. These user fees must be paid at the time of the first submission of the application, even if the application is being submitted on a rolling basis. Fee waivers or reductions are available in certain circumstances. One basis for a waiver of the application user fee is if the applicant employs fewer than 500 employees, including employees of affiliates, the applicant does not have an approved marketing application for a product that has been introduced or delivered for introduction into interstate commerce, and the applicant, including its affiliates, is submitting its first marketing application. Product candidates that are designated as orphan products, which are further described below, are also not subject to application user fees unless the application includes an indication other than the orphan indication.

In addition, under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA for a new active ingredient, indication, dosage form, dosage regimen, or route of administration, must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Also, under the FDA Reauthorization Act of 2017, beginning in 2020, for applications for product candidates intended for the treatment of adult cancer which are directed at molecular targets that the FDA determines to be substantially relevant to the growth or progression of pediatric cancer, in place of the PREA investigations, sponsors must submit, with the application, reports from molecularly targeted pediatric cancer investigations designed to yield clinically meaningful pediatric study data, using appropriate formulations, to inform potential pediatric labeling. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Orphan products are also exempt from the PREA requirements.

The FDA also may require submission of a REMS to ensure that the benefits of the biologic outweigh the risks. The REMS plan could include medication guides, physician communication plans, and elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools. An assessment of the REMS must also be conducted at set intervals. Following product approval, a REMS may also be required by the FDA if new safety information is discovered and the FDA determines that a REMS is necessary to ensure that the benefits of the biologic outweigh the risks.

Once the FDA receives an application, it has 60 days to review the BLA to determine if it is substantially complete to permit a substantive review before it accepts the application for filing. The FDA may request additional information rather than accept a BLA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review.

Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has set the review goal of completing its review of 90% of all applications within ten months from the 60-day filing date for its initial review of a BLA. This review goal is referred to as the PDUFA date. The PDUFA date is only a goal, thus, the FDA does not always meet its PDUFA dates. The review process and the PDUFA date may also be extended if the FDA requests or the sponsor otherwise provides substantial additional information or clarification regarding the submission.

The FDA may also refer certain applications to an advisory committee. Before approving a biologic for which no active ingredient, including any ester or salt of active ingredients, has previously been approved by the FDA, the FDA must either refer that biologic to an external advisory committee

or provide in an action letter, a summary of the reasons why the FDA did not refer the product candidate to an advisory committee. An advisory committee is typically a panel that includes clinicians and other experts, which review, evaluate, and make a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

The FDA reviews applications to determine, among other things, whether a product is safe, pure and potent and whether the manufacturing methods and controls are adequate to assure and preserve the product's identity, strength, quality, potency, and purity. Before approving a BLA, the FDA typically will inspect the facility or facilities where the product is manufactured, referred to as a Pre-Approval Inspection. The FDA will not approve an application unless it determines that the manufacturing processes and facilities, including contract manufacturers and subcontractors, are in compliance with current cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA the FDA will inspect one or more clinical trial sites to assure compliance with GCPs.

After evaluating the BLA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a Complete Response Letter, or CRL. A CRL indicates that the review cycle of the application is complete and the application is not ready for approval, and describes all of the specific deficiencies that the FDA identified in the BLA. A CRL generally contains a statement of specific conditions that must be met in order to secure final approval of the BLA and may require additional clinical or preclinical testing in order for the FDA to reconsider the application. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. If a CRL is issued, the applicant may either: resubmit the BLA, addressing all of the deficiencies identified in the letter; withdraw the application; or request an opportunity for a hearing. The FDA has the goal of reviewing 90% of application resubmissions in either two or six months of the resubmission date, depending on the kind of resubmission. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA may issue an approval letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings, or precautions be included in the product labeling, including a boxed warning, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a product's safety and efficacy after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms under a REMS which can materially affect the potential market and profitability of the product. The FDA may also not approve label statements that are necessary for successful commercialization and marketing.

After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval. The FDA may also withdraw the product approval if compliance with the pre- and post-marketing regulatory standards are not maintained or if problems occur after the product reaches the marketplace. Further, should new safety information arise, additional testing, product labeling, or FDA notification may be required.

Broadly equivalent requirements and controls similarly apply to the submission of marketing authorization applications to the European Medicines Agency in the European Union and, post-approval, to the holding of such marketing authorizations.

Biosimilars and exclusivity

The BPCIA creates an abbreviated approval pathway for biological products shown to be highly similar to or interchangeable with an FDA-licensed reference biological product. Biosimilarity sufficient to reference a prior FDA-approved product requires a high similarity to the reference product notwithstanding minor differences in clinically inactive components, and no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. Biosimilarity must be shown through analytical studies, animal studies, and at least one clinical trial, absent a waiver by the FDA. There must be no difference between the reference product and a biosimilar in mechanism of action, conditions of use, route of administration, dosage form, and strength. A biosimilar product may be deemed interchangeable with a prior approved product if it meets the higher hurdle of demonstrating that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biosimilar and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

A reference biologic is granted 12 years of exclusivity from the time of first licensure of the reference product, and no application for a biosimilar can be submitted for four years from the date of licensure of the reference product. However, certain changes and supplements to an approved BLA, and subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest, or other related entity do not qualify for the twelve-year exclusivity period. The PHSA also includes provisions to protect reference products that have patent protection. The biosimilar product sponsor and reference product sponsor may exchange certain patent and product information for the purpose of determining whether there should be a legal patent challenge. Based on the outcome of negotiations surrounding the exchanged information, the reference product sponsor may bring a patent infringement suit and injunction proceedings against the biosimilar product sponsor. The biosimilar applicant may also be able to bring an action for declaratory judgment concerning the patent.

In the European Union there is a period of 10 years (or 11 years for significant new indications) of data exclusivity so that those seeking to market biosimilars cannot apply on an abridged basis for a marketing authorization for eight years from when the product was first marketed in the European Union and cannot place it on the market for 10 or 11 years from such first marketing.

If approved, biologics may also be eligible for periods of United States patent term restoration. If granted, patent term restoration extends the patent life of a single unexpired patent, that has not previously been extended, for a maximum of five years. The total patent life with the extension also cannot exceed fourteen years from the product's approval date. Subject to the prior limitations, the period of the extension is calculated by adding half of the time from the effective date of an IND to the initial submission of a marketing application, and all of the time between the submission of the marketing application and its approval. This period may also be reduced by any time that the applicant did not act with due diligence.

In the European Union, a supplementary protection certificate, or SPC, can similarly extend a patent term for a maximum of five years. A six-month additional extension, however, is available if the SPC relates to a medicinal product for which data has been submitted according to a Pediatric Investigation Plan.

Post-approval requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements related to manufacturing, recordkeeping, and reporting, including adverse experience reporting, deviation reporting, shortage reporting, and periodic reporting, product distribution, advertising, marketing, promotion, certain electronic records and signatures, and post-approval obligations imposed as a

condition of approval, such as Phase 4 clinical trials, REMS, and surveillance to assess safety and effectiveness after commercialization.

After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing annual program user fee requirements for approved products, excluding, under certain circumstances, orphan products. In addition, manufacturers and other entities involved in the manufacture and distribution of approved therapeutics are required to register their establishments with the FDA and certain state agencies, list their products, and are subject to periodic announced and unannounced inspections by the FDA and these state agencies for compliance with current cGMP and other requirements, which impose certain procedural and documentation requirements upon us and third-party manufacturers. Manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with current cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Changes to the manufacturing process are strictly regulated and often require prior FDA approval or notification before being implemented. FDA regulations also require investigation and correction of any deviations from current cGMP and specifications and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain current cGMP compliance.

The FDA also strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. A company can make only those claims relating to safety and efficacy, purity, and potency that are approved by the FDA. Physicians, in their independent professional medical judgment, may prescribe legally available products for unapproved indications that are not described in the product's labeling and that differ from those tested and approved by the FDA. Biopharmaceutical companies, however, are required to promote their products only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including, but not limited to, criminal and civil penalties under the FDCA and False Claims Act, exclusion from participation in federal healthcare programs, mandatory compliance programs under corporate integrity agreements, suspension and debarment from government contracts, and refusal of orders under existing government contracts.

Moreover, the enacted Drug Quality and Security Act imposes obligations on manufacturers of biopharmaceutical products related to product tracking and tracing. Among the requirements of this legislation, manufacturers are required to provide certain information regarding the products to individuals and entities to which product ownership is transferred, will be required to label products with a product identifier, and are required to keep certain records regarding the product. The transfer of information to subsequent product owners by manufacturers is also required to be done electronically. Manufacturers must also verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this legislation, manufactures have product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products that would result in serious adverse health consequences or death to humans, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death. Similar requirements additionally are and will be imposed through this legislation on other companies within the biopharmaceutical product supply chain, such as distributors and dispensers.

Adverse event reporting and submission of periodic reports, including annual reports and deviation reports, are required following FDA approval of a BLA. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in significant regulatory actions. Such actions may include refusal to approve pending applications, license suspension or revocation, imposition of a clinical hold or termination of clinical trials, warning letters, untitled letters, cyber letters, modification of promotional materials or labeling, provision of corrective information, imposition of post-market requirements including the need for additional testing, imposition of distribution or other restrictions under a REMS, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, FDA debarment, injunctions, fines, consent decrees, corporate integrity agreements, suspension and debarment from government contracts, refusal of orders under existing government contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement, or civil or criminal penalties, including fines and imprisonment, and result in adverse publicity, among other adverse consequences.

Additional controls for biologics

To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer.

In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products.

Fraud and abuse, data privacy and security, and transparency laws and regulations

Our business activities, including but not limited to, research, sales, promotion, distribution, medical education, and other activities following product approval will be subject to regulation by numerous federal and state regulatory and law enforcement authorities in the United States in addition to the FDA, including potentially the Department of Justice, the Department of Health and Human Services and its various divisions, including the CMS and the Health Resources and Services Administration, the Department of Veterans Affairs, the Department of Defense, and state and local governments. Our business activities must comply with numerous healthcare laws, including but not limited to, anti-kickback and false claims laws and regulations as well as data privacy and security laws and regulations, which are described below, as well as state and federal consumer protection and unfair competition laws.

The federal Anti-Kickback Statute, which regulates, among other things, marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting, or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to

induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order, or the referral to another for the furnishing or arranging for the furnishing of any item or service reimbursable under Medicare, Medicaid, or other federal healthcare programs, in whole or in part. The term "remuneration" has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between biopharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers, and beneficiaries on the other, as well as free trial and starter prescriptions provided through pharmacies. There are certain statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly, and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of the facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The ACA modified the intent requirement under the Anti-Kickback Statute to a stricter standard, such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA also provided that a violation of the federal Anti-Kickback Statute is grounds for the government or a whistleblower to assert that a claim for payment of items or services resulting from such violation constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or avoiding, decreasing, or concealing an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. The civil False Claims Act has been used to assert liability on the basis of kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, improper use of Medicare provider or supplier numbers when detailing a provider of services, improper promotion of off-label uses not expressly approved by the FDA in a product's label, and allegations as to misrepresentations with respect to the services rendered. In addition, private payers have been filing follow-on lawsuits alleging fraudulent misrepresentation, although establishing liability and damages in these cases is more difficult than under the civil False Claims Act. Intent to deceive is not required to establish liability under the civil False Claims Act. Civil False Claims Act actions may be brought by the government or may be brought by private individuals on behalf of the government, called "qui tam" actions. If the government decides to intervene in a qui tam action and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. The civil False Claims Act provides for treble damages and a civil penalty for each false claim, such as an invoice or pharmacy claim for reimbursement, which can aggregate into millions of dollars. For these reasons, since 2004, civil False Claims Act lawsuits against biopharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements, as much as $3.0 billion, regarding certain sales practices and promoting off label uses. Civil False Claims Act liability may further be imposed for known Medicare or Medicaid overpayments, for example, overpayments caused by understated rebate amounts, that are not refunded within 60 days of discovering the overpayment, even if the overpayment was not caused by a false or fraudulent act. In addition, conviction or civil judgment for violating the civil False Claims Act may result in exclusion from federal health care programs, and

suspension and debarment from government contracts, and refusal of orders under existing government contracts.

The government may further prosecute conduct constituting a false claim under the criminal False Claims Act. The criminal False Claims Act prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious, or fraudulent and, unlike the civil False Claims Act, requires proof of intent to submit a false claim.

The civil monetary penalties statute is another potential statute under which biopharmaceutical companies may be subject to enforcement. Among other things, the civil monetary penalties statute imposes fines against any person who is determined to have knowingly presented, or caused to be presented, claims to a federal healthcare program that the person knows, or should know, is for an item or service that was not provided as claimed or is false or fraudulent.

Payment or reimbursement of prescription therapeutics by Medicaid or Medicare requires manufacturers to submit certified pricing information to CMS. The Medicaid Drug Rebate statute requires manufacturers to calculate and report price points, which are used to determine Medicaid rebate payments shared between the states and the federal government and Medicaid payment rates for certain therapeutics. For therapeutics paid under Medicare Part B, manufacturers must also calculate and report their Average Sales Price, which is used to determine the Medicare Part B payment rate. In addition, therapeutics covered by Medicaid are subject to an additional inflation penalty which can substantially increase rebate payments. For products approved under a BLA (including biosimilars), or an NDA, the VHCA requires manufacturers to calculate and report to the Veterans Administration, or VA, a different price called the Non-Federal Average Manufacturing Price, which is used to determine the maximum price that can be charged to certain federal agencies, referred to as the Federal Ceiling Price, or FCP. Like the Medicaid rebate amount, the FCP includes an inflation penalty. A Department of Defense regulation requires manufacturers to provide this discount on therapeutics dispensed by retail pharmacies when paid by the TRICARE Program. All of these price reporting requirements create risk of submitting false information to the government, and potential FCA liability.

The VHCA also requires manufacturers of covered therapeutics participating in the Medicaid program to enter into Federal Supply Schedule contracts with the VA through which their covered therapeutics must be sold to certain federal agencies at FCP. This necessitates compliance with applicable federal procurement laws and regulations, including submission of commercial sales and pricing information, and subjects us to contractual remedies as well as administrative, civil, and criminal sanctions. In addition, the VHCA requires manufacturers participating in Medicaid to agree to provide different mandatory discounts to certain Public Health Service grantees and other safety net hospitals and clinics under the 340B program based on the manufacturer's reported Medicaid pricing information. The 340B program has its own regulatory authority to impose sanctions for non-compliance and adjudicate overcharge claims against manufacturers by the purchasing entities.

The federal Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA, also created federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, a healthcare benefit program, regardless of whether the payor is public or private, in connection with the delivery or payment for health care benefits, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters. Additionally, the ACA amended the intent requirement of certain of these criminal statutes under HIPAA so that a person or

entity no longer needs to have actual knowledge of the statute, or the specific intent to violate it, to have committed a violation.

The ACA further created new federal requirements for reporting, by applicable manufacturers of covered therapeutics, payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members.

Further, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by HITECH, and its respective implementing regulations imposes certain requirements on covered entities relating to the privacy, security, and transmission of certain individually identifiable health information known as protected health information. Among other things, HITECH, through its implementing regulations, makes HIPAA's security standards and certain privacy standards directly applicable to business associates, defined as a person or organization, other than a member of a covered entity's workforce, that creates, receives, maintains, or transmits protected health information on behalf of a covered entity for a function or activity regulated by HIPAA. HITECH also strengthened the civil and criminal penalties that may be imposed against covered entities, business associates, and individuals, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, other federal and state laws may govern the privacy and security of health and other information in certain circumstances, many of which differ from each other in significant ways and may not be preempted by HIPPA, thus complicating compliance efforts.

Many states have also adopted laws similar to each of the above federal laws, which may be broader in scope and apply to items or services reimbursed by any third-party payor, including commercial insurers. Certain state laws also regulate manufacturers' use of prescriber-identifiable data. Certain states also require implementation of commercial compliance programs and compliance with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments or the provision of other items of value that may be made to healthcare providers and other potential referral sources; impose restrictions on marketing practices; or require manufacturers to track and report information related to payments, gifts, and other items of value to physicians and other healthcare providers. Recently, states have enacted or are considering legislation intended to make drug prices more transparent and deter significant price increases. These laws may affect our future sales, marketing, and other promotional activities by imposing administrative and compliance burdens.

If our operations are found to be in violation of any of the laws or regulations described above or any other laws that apply to us, we may be subject penalties or other enforcement actions, including criminal and significant civil monetary penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, corporate integrity agreements, suspension and debarment from government contracts, and refusal of orders under existing government contracts, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals. In the European Union, the data privacy laws are generally perceived to be stricter than those which apply in the United States and include specific requirements for the transfer of personal data outside the European Union

to the United States to ensure that European Union standards of data privacy will be applied to such data.

Coverage and reimbursement generally

The commercial success of our product candidates and our ability to commercialize any approved product candidates successfully will depend in part on the extent to which governmental payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers, and other third-party payors, provide coverage for and establish adequate reimbursement levels for our product candidates. Government authorities, private health insurers, and other organizations generally decide which therapeutics they will pay for and establish reimbursement levels for healthcare. Medicare is a federally funded program managed by CMS through local fiscal intermediaries and carriers that administer coverage and reimbursement for certain healthcare items and services furnished to the elderly and disabled. Medicaid is an insurance program for certain categories of patients whose income and assets fall below state defined levels and who are otherwise uninsured that is both federally and state funded and managed by each state. The federal government sets general guidelines for Medicaid and each state creates specific regulations that govern its individual program, including supplemental rebate programs that restrict coverage to therapeutics on the state Preferred Drug List. Similarly, government laws and regulations establish the parameters for coverage of prescription therapeutics by health plans participating in state exchanges and Tricare, the health care program for military personnel, retirees, and related beneficiaries. Some states have also created pharmacy assistance programs for individuals who do not qualify for federal programs. In the United States, private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government provides reimbursement through the Medicare or Medicaid programs for such products and services.

In the United States, the European Union, and other potentially significant markets for our product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which often has resulted in average selling prices lower than they would otherwise be and sometimes at or below the provider's acquisition cost. In the United States, it is also common for government and private health plans to use coverage determinations to leverage rebates from manufacturers in order to reduce the plans' net costs. These restrictions and limitations influence the purchase of healthcare services and products and lower the realization on manufacturers' sales of prescription therapeutics. Third-party payors are developing increasingly sophisticated methods of controlling healthcare costs. Third-party payors may limit coverage to specific therapeutic products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication or might impose high copayment amounts to influence patient choice. Third-party payors also control costs by requiring prior authorization or imposing other dispensing restrictions before covering certain products and by broadening therapeutic classes to increase competition. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. Absent clinical differentiators, third-party payors may treat products as therapeutically equivalent and base formulary decisions on net cost. To lower the prescription cost, manufacturers frequently rebate a portion of the prescription price to the third-party payors. Recently, purchasers and third-party payors have begun to focus on value of new therapeutics and sought agreements in which price is based on achievement of performance metrics.

Federal programs also impose price controls through mandatory ceiling prices on purchases by federal agencies and federally funded hospitals and clinics and mandatory rebates on retail pharmacy prescriptions paid by Medicaid and Tricare. These restrictions and limitations influence the purchase of healthcare services and products. Legislative proposals to reform healthcare or reduce costs under

government programs may result in lower reimbursement for our product candidates or exclusion of our product candidates from coverage. In addition, government programs like Medicaid include substantial penalties for increasing commercial prices over the rate of inflation which can affect realization and return on investment.

Private payors often rely on the lead of the governmental payors in rendering coverage and reimbursement determinations. Therefore, achieving favorable CMS coverage and reimbursement is usually a significant gating issue for successful introduction of a new product. In addition, many government programs as a condition of participation mandate fixed discounts or rebates from manufacturers regardless of formulary position or utilization, and then rely on competition in the market to attain further price reductions, which can greatly reduce realization on the sale.

Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement, and utilization, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, competition within therapeutic classes, judicial decisions and governmental laws and regulations related to Medicare, Medicaid, and healthcare reform, biopharmaceutical coverage and reimbursement policies, and pricing in general. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Sales of our product candidates will therefore depend substantially, both domestically and abroad, on the extent to which the costs of our products will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, such as Medicare and Medicaid, private health insurers, and other third-party payors.

As a result of the above, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective, or the rebate percentages required to secure coverage may not yield an adequate margin over cost.

Moreover, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in therapeutic development. Legislative proposals to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for our products and product candidates or exclusion of our products and product candidates from coverage. The cost containment measures that healthcare payors and providers are instituting and any healthcare reform could significantly reduce our revenues from the sale of any approved product candidates. We cannot provide any assurances that we will be able to obtain and maintain third-party coverage or adequate reimbursement for our product candidates in whole or in part.

The absence in Europe of any substantive harmonization of pricing and reimbursement regimes, including health technology assessment, means that separate negotiations will need to take place with the relevant authorities in each member state.

Healthcare reform measures

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals designed to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality, and expanding access. In the United States, the

biopharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, Medicare Part B, which covers products administered by physicians in an outpatient setting, may be undergoing a significant change in payment rates. CMS has proposed a rule that would compensate physicians for therapeutics they administer based on a smaller mark-up over the manufacturer's Average Sales Price and a fixed fee, which is intended to incentivize physicians to purchase and bill Medicare for lower priced products. The proposed rule would also authorize CMS to establish methods for determining comparative cost effectiveness and seek value-based discounts

Similarly, the American Recovery and Reinvestment Act of 2009 established funding for the federal government to compare the effectiveness of different treatments for the same illness. The Agency for Healthcare Research and Quality conducts patient-centered outcome research, develops evidence-based tools and resources on medication therapies, maintains databases of health care related data and standards, and issues periodic reports on specific studies. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the organization's research has had or will have on the sales of any product, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates. If third-party payors do not consider our product candidates to be cost-effective compared to other available therapies, they may not cover our product candidates, once approved, as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

Moreover, the ACA broadened access to health insurance, attempts to reduce or constrain the growth of healthcare spending, enhanced remedies against fraud and abuse, added new transparency requirements for healthcare and health insurance industries, imposed new taxes and fees on the health care industry, and imposed additional health policy reforms. The law expanded the eligibility criteria and mandatory eligibility categories for Medicaid programs, thereby potentially increasing both the volume of sales and manufacturers' Medicaid rebate liability. The law also expanded the 340B discount program that mandates discounts to certain hospitals, community centers, and other qualifying providers, by expanding the categories of entities eligible to purchase under the program, although, with the exception of children's hospitals, these newly eligible entities are ineligible to receive discounted 340B pricing on orphan therapeutics used to treat an orphan disease or condition. The ACA revised the definition of "average manufacturer price", or AMP, for reporting purposes, which generally increased the amount of Medicaid rebates to states and created a separate AMP for certain categories of therapeutics provided in non-retail outpatient settings. The law additionally extended manufacturer's Medicaid rebate liability to covered therapeutics dispensed to patients enrolled in Medicaid managed care organizations and increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate program. The revisions to the AMP definition and Medicaid rebate formula can have the further effect of increasing the required 340B discounts. Further, the ACA requires manufacturers of therapeutics to pay 50% of the pharmacy charge to Medicare Part D patients while they are in the coverage gap, and this percentage was increased to 70% by the Bipartisan Budget Act of 2018. Finally, the ACA imposes a significant annual fee on companies that manufacture or import branded prescription therapeutic products. Substantial new provisions affecting compliance have also been enacted through the ACA and otherwise, including the reporting of therapeutic sample distribution, which may require us to modify our business practices with healthcare practitioners. Although the ACA was recently amended to repeal the individual insurance mandate, and efforts to repeal and replace portions of the law may continue, it is likely that pressure on biopharmaceutical pricing, especially under the Medicare program, will continue, and may also increase our regulatory burdens and operating costs. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our product

candidates. Recently, CMS issued regulations reducing Medicare Part B payments to certain hospitals for outpatient therapeutics purchased under the 340B program.

The cost of biopharmaceuticals continues to generate substantial governmental and third-party payor interest. We expect that the biopharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Our results of operations could be adversely affected by current and future healthcare reforms.

Some third-party payors also require pre-approval of coverage for new or innovative devices or therapies before they will reimburse healthcare providers that use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. The Budget Control Act of 2011, as amended, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee on Deficit Reduction did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year. The Bipartisan Budget Act of 2018 retained the federal budget "sequestration" Medicare payment reductions of 2%, and extended it through 2027. The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These and other healthcare reform initiatives may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our financial operations. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could further limit the prices we are able to charge, or the amounts of reimbursement available, for our product candidates once they are approved. The Bipartisan Budget Act also extended Manufacturer responsibility for prescription costs in the Medicare Part D coverage gap to biosimilars, which had previously been exempt.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight, and suspension and debarment from government contracts, and refusal of orders under existing government contracts.

Other foreign anti-corruption regimes are arguably of wider application. For instance, the U.K. Bribery Act 2010 applies to dealings with any decision maker whether in the private or public sector in a position of trust.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K, including our audited consolidated financial statements and related notes and "Management's Discussion and Analysis of Results of Operations and Financial Condition." If any of the following risks are realized, our business, financial condition, operating results and prospects could be materially and adversely affected. In that event, the price of our common stock could decline, and you could lose part or all of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business.

Risks related to product development

Our product candidates are in the early stages of development, are not approved for commercial sale and might never receive regulatory approval or become commercially viable. We have never generated any revenue from product sales and may never be profitable.

All of our product candidates are in research or early development. We have not generated any revenues from the sale of products and do not expect to do so for at least the next several years. Our lead product candidate, RP1, and any other product candidates will require extensive preclinical and/or clinical testing and regulatory approval prior to commercial use. Our research and development efforts may not be successful. Even if our clinical development efforts result in positive data, our product candidates may not receive regulatory approval or be successfully introduced and marketed at prices that would permit us to operate profitably.

We currently have only one product candidate, RP1, in clinical development. A failure of this product candidate in clinical development would adversely affect our business and may require us to discontinue development of other product candidates based on the same therapeutic approach.

RP1 is our only clinical development-stage product candidate. Although we have other product candidates, RP2 and RP3, in preclinical development and we intend to develop additional product candidates in the coming years, it will take additional investment and time for such product candidates to reach the same stage of development as RP1, and there can be no assurance that they will ever do so. Since all of the product candidates in our current pipeline are based on our Immulytic platform, if RP1 fails in development as a result of any underlying problem with our Immulytic platform, then we may be required to discontinue development of all product candidates that are based on our therapeutic approach. If we were required to discontinue development of RP1 or our other product candidates, or if any of them were to fail to receive regulatory approval or achieve sufficient market acceptance, we could be prevented from or significantly delayed in achieving profitability. We can provide no assurance that we would be successful at developing other product candidates based on an alternative therapeutic approach.

We will not be able to commercialize our product candidates if our preclinical studies do not produce successful results and/or our clinical trials do not demonstrate the safety and efficacy of our product candidates.

Our lead product candidate, RP1, is in an ongoing Phase 1/2 clinical trial alone and in combination with nivolumab, and we expect to initiate a Phase 2 clinical trial of RP1 in combination with cemiplimab in CSCC in August 2019. While our other product candidates, RP2 and RP3, are in pre-clinical development, subject to regulatory clearance, we expect RP2 to begin a Phase 1/2 clinical trial in the third quarter of 2019 and expect RP3 to enter clinical development in 2020. Our product

candidates will require preclinical and clinical trials before we can submit a marketing application to the applicable regulatory authorities.

Our product candidates are susceptible to the risks of failure inherent at any stage of product development, including the occurrence of unexpected or unacceptable adverse events or the failure to demonstrate efficacy in clinical trials. Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain.

The results of preclinical studies, preliminary study results, and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Our product candidates may not perform as we expect, may ultimately have a different or no impact on tumors, may have a different mechanism of action than we expect in humans, and may not ultimately prove to be safe and effective.

Preliminary and final results from preclinical studies and early stage trials, and trials in compounds that we believe are similar to ours, may not be representative of results that are found in larger, controlled, blinded, and longer-term studies. Product candidates may fail at any stage of preclinical or clinical development. Product candidates may fail to show the desired safety and efficacy traits even if they have progressed through preclinical studies or initial clinical trials. Preclinical studies and clinical trials may also reveal unfavorable product candidate characteristics, including safety concerns. A number of companies in the biopharmaceutical industry have suffered significant setbacks in clinical trials, notwithstanding promising results in earlier preclinical studies or clinical trials or promising mechanisms of action. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Moreover, should there be an issue with the design of a clinical trial, our results may be impacted. We may not discover such a flaw until the clinical trial is at an advanced stage.

We may also experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or institutional review boards, or IRBs, may not authorize us or our investigators to commence a clinical trial, conduct a clinical trial at a prospective trial site, or amend trial protocols, or may require that we modify or amend our clinical trial protocols;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and/or CROs;
- clinical trials of our product candidates may produce negative or inconclusive results, or our studies may fail to reach the necessary level of statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or be lost to follow-up at a higher rate than we anticipate, or may elect to participate in alternative clinical trials sponsored by our competitors with product candidates that treat the same indications as our product candidates;
- our third-party contractors may fail to comply with regulatory requirements or the clinical trial protocol, or meet their contractual obligations to us in a timely manner, or at all, or we may be required to engage in additional clinical trial site monitoring;

- we, regulators, or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks, undesirable side effects, or other unexpected characteristics of the product candidate, or due to findings of undesirable effects caused by a chemically or mechanistically similar therapeutic or therapeutic candidate;
- changes could be adopted in marketing approval policies during the development period, rendering our data insufficient to obtain marketing approval;
- statutes or regulations could be amended or new ones could be adopted;
- changes could be adopted in the regulatory review process for submitted product applications;
- the cost of clinical trials of our product candidates may be greater than we anticipate or we may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA upon the filing of a Biologics License Application, or BLA, or equivalent authorizations from comparable foreign regulatory authorities;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- we may decide, or regulators may require us, to conduct or gather, as applicable, additional clinical trials, analyses, reports, data, or preclinical trials, or we may abandon product development programs;
- we may fail to reach an agreement with regulators or IRBs regarding the scope, design, or implementation of our clinical trials, and the FDA or comparable foreign regulatory authorities may require changes to our study designs that make further study impractical or not financially prudent;
- regulators may ultimately disagree with the design or our conduct of our preclinical studies or clinical trials, finding that they do not support product candidate approval;
- we may have delays in adding new investigators or clinical trial sites, or we may experience a withdrawal of clinical trial sites;
- patients that enroll in our studies may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the study or clinical trial, increase the needed enrollment size for the clinical trial or extend its duration;
- there may be regulatory questions or disagreements regarding interpretations of data and results;
- the FDA or comparable foreign regulatory authorities may disagree with our study design, including endpoints, or our interpretation of data from preclinical studies and clinical trials or find that a product candidate's benefits do not outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may not accept data from studies with clinical trial sites in foreign countries;
- the FDA or comparable foreign regulatory authorities may disagree with our intended indications;
- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or our manufacturing facilities for clinical and future commercial supplies;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission

of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;

- the FDA or comparable foreign regulatory authorities may take longer than we anticipate to make a decision on our product candidates; and
- we may not be able to demonstrate that a product candidate provides an advantage over current standards of care or current or future competitive therapies in development.

Our development costs will also increase if we experience delays in testing or approvals, and we may not have sufficient funding to complete the testing and approval process for any of our product candidates. We may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of our product candidates. We do not know whether any preclinical tests or clinical trials beyond what we currently have planned will be required, will begin as planned, will need to be restructured, or will be completed on schedule, or at all. Significant delays relating to any preclinical or clinical trials also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays in clinical trials may ultimately lead to the denial of marketing approval of any of our product candidates. If any of these occur, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

We anticipate that our product candidates will be used in combination with third-party drugs, some of which are still in development, and we have limited or no control over the supply, regulatory status, or regulatory approval of such drugs.

Our product candidates are intended to be administered in combination with checkpoint blockade drugs, a class of drugs that are intended to stop tumor cells from "switching off" an immune system attack against themselves. We have entered into an agreement with BMS for the supply of nivolumab, its anti-PD-1 therapy, for use in connection with our current Phase 1/2 clinical trial with RP1. We have also entered into a clinical collaboration agreement with Regeneron, which includes the supply of cemiplimab, its anti-PD-1 therapy, for clinical trials conducted under the Regeneron agreement. We are currently initiating the first planned clinical trial under the agreement, a randomized, controlled Phase 2 clinical trial of RP1 in combination with cemiplimab, versus cemiplimab alone, in approximately 240 patients with CSCC. We may enter into additional agreements for the supply of anti-PD-1 products for use in connection with the development of one or more of our product candidates. Our ability to develop and ultimately commercialize our product candidates used in combination with nivolumab, cemiplimab or any other checkpoint blockade therapy will depend on our ability to access such drugs on commercially reasonable terms for the clinical trials and their availability for use with the commercialized product, if approved. We cannot be certain that current or potential future commercial relationships will provide us with a steady supply of such drugs on commercially reasonable terms or at all.

Any failure to maintain or enter into new successful commercial relationships, or the expense of purchasing checkpoint blockade therapies in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop our product candidates as commercially viable therapies. If any of these occur, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. We are developing RP1 and our other product candidates for use in combination with anti-PD-1 or anti-PD-L1 therapies and may develop RP1 or our other product candidates for use with other therapies. The FDA may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of these trials could show that any positive previous trial results are attributable to the combination therapy and not our product candidates. Moreover, following product approval, the FDA may require that products used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to the other product, this may require us to work with a third party to satisfy such a requirement. Moreover, developments related to the other product may impact our clinical trials for the combination as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the other product's safety or efficacy profile, changes to the availability of the approved product, and changes to the standard of care.

In the event that BMS, Regeneron or any future collaborator or supplier cannot continue to supply their products on commercially reasonable terms, we would need to identify alternatives for accessing an anti-PD-1 therapy. Additionally, should the supply of products from BMS, Regeneron or any future collaborator or supplier be interrupted, delayed or otherwise be unavailable to us, our clinical trials may be delayed. In the event we are unable to source a supply of an alternative anti-PD-1 therapy, or are unable to do so on commercially reasonable terms, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

If we fail to develop additional product candidates, our commercial opportunity could be limited.

Our lead product candidate is RP1. A key part of our strategy is to pursue clinical development of RP1 and additional product candidates, RP2 and RP3. Developing, obtaining marketing approval for, and commercializing additional product candidates will require substantial additional funding and will be subject to the risks of failure inherent in medical product development. We cannot assure our shareholders that we will be able to successfully advance any of these additional product candidates through the development process.

Even if we obtain approval from the FDA or comparable foreign regulatory authorities to market additional product candidates for the treatment of solid tumors, we cannot assure our shareholders that any such product candidates will be successfully commercialized, widely accepted in the marketplace, or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates, our commercial opportunity may be limited and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Risks related to regulatory approval

Even if our development efforts are successful, we may not obtain regulatory approval for any of our product candidates in the United States or other jurisdictions, which would prevent us from commercializing our product candidates. Even if we obtain regulatory approval for our product candidates, any such approval may be subject to limitations, including with respect to the approved indications or patient populations, which could impair our ability to successfully commercialize our product candidates.

We are not permitted to market or promote or sell any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy for that indication. Securing marketing approval also requires the submission of information

about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by, the regulatory authorities. If we do not receive approval from the FDA and comparable foreign regulatory authorities for any of our product candidates, we will not be able to commercialize such product candidates in the United States or in other jurisdictions. If significant delays in obtaining approval for and commercializing our product candidates occur in any jurisdictions, our business, financial condition, results of operations, stock price and prospects will be materially harmed. Even if our product candidates are approved, they may:

- be subject to limitations on the indicated uses or patient populations for which they may be marketed, distribution restrictions, or other conditions of approval;
- contain significant safety warnings, including boxed warnings, contraindications, and precautions;
- not be approved with label statements necessary or desirable for successful commercialization; or
- contain requirements for costly post-market testing and surveillance, or other requirements, including the submission of a risk evaluation and mitigation strategy, or REMS, to monitor the safety or efficacy of the products.

We have not previously submitted a BLA to the FDA, or a similar marketing application to comparable foreign regulatory authorities, for any product candidate, and we can provide no assurance that we will ultimately be successful in obtaining regulatory approval for claims that are necessary or desirable for successful marketing, or at all.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain, or experience delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates as expected, and our ability to generate revenue may be materially impaired.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions and there may be varying interpretations of data obtained from preclinical studies or clinical trials, any of which may cause delays or limitations in the approval or a decision not to approve an application. These regulatory requirements may require us to amend our clinical trial protocols, conduct additional preclinical studies or clinical trials that may require regulatory or IRB approval, or otherwise cause delays in the approval or rejection of an application. Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability to generate revenue from the particular product candidate, which may materially harm our business, financial condition, results of operations, stock price and prospects.

If we experience delays in obtaining approval, if we fail to obtain approval of a product candidate or if the label for a product candidate does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate, the commercial prospects for such product candidate may be harmed and our ability to generate revenues from that product candidate may be materially impaired.

The FDA or a comparable foreign regulatory authority may determine that our product candidates have undesirable side effects that could delay or prevent their regulatory approval or commercialization.

To date, the most commonly reported adverse events observed for RP1 are local injection site reactions and systemic constitutional symptoms, such as fatigue, fevers and chills. However, there can be no assurance that additional undesirable side effects or serious adverse events will not be caused by

or associated with RP1 or our other product candidates as they continue through or enter clinical development. Serious adverse events or undesirable side effects caused by our product candidates could cause us, IRBs, and other reviewing entities or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. For example, if concerns are raised regarding the safety of a new therapeutic as a result of undesirable side effects identified during clinical or preclinical testing, the FDA or comparable foreign regulatory authority may order us to cease further development, decline to approve the product candidate or issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve the product candidate. The FDA or comparable foreign regulatory authorities, or IRBs and other reviewing entities, may also require, or we may voluntarily develop, strategies for managing adverse events during clinical development, which could include restrictions on our enrollment criteria, the use of stopping criteria, adjustments to a study's design, or the monitoring of safety data by a data monitoring committee, among other strategies. FDA or comparable foreign regulatory authority requests for additional data or information could also result in substantial delays in the approval of our product candidates.

Undesirable side effects caused by any of our product candidates could also result in denial of regulatory approval by the FDA or comparable foreign regulatory authorities for any or all targeted indications or the inclusion of unfavorable information in our product labeling, such as limitations on the indicated uses for which the products may be marketed or distributed, a label with significant safety warnings, including boxed warnings, contraindications, and precautions, a label without statements necessary or desirable for successful commercialization, or may result in requirements for costly post-marketing testing and surveillance, or other requirements, including REMS, to monitor the safety or efficacy of the products, and in turn prevent us from commercializing and generating revenues from the sale of our product candidates. Undesirable side effects may limit the potential market for any approved products or could result in the discontinuation of the sales and marketing of the product, or withdrawal of product approvals. Later discovered undesirable side effects may further result in the imposition of a REMS, label revisions, post-approval study requirements, or other testing and surveillance.

If any of our product candidates is associated with serious adverse events or undesirable side effects or have properties that are unexpected, we may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The therapeutic-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may materially harm our business, financial condition, results of operations, stock price and prospects.

Changes in product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates are developed through preclinical studies to later-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, or notification to, or approval by the FDA or a comparable foreign regulatory authority. This could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and/or jeopardize our ability to commence product sales and generate revenue.

Regulatory approval by the FDA or comparable foreign regulatory authorities is limited to those specific indications and conditions for which approval has been granted, and we may be subject to substantial fines, criminal penalties, injunctions, or other enforcement actions if we are determined to be promoting the use of our products for unapproved or "off-label" uses, resulting in damage to our reputation and business.

We must comply with requirements concerning advertising and promotion for any product candidates for which we obtain marketing approval. Promotional communications with respect to therapeutics are subject to a variety of legal and regulatory restrictions and continuing review by the FDA, Department of Justice, Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress, and the public. When the FDA or comparable foreign regulatory authorities issue regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a product is approved. If we are not able to obtain FDA approval for desired uses or indications for our product candidates, we may not market or promote them for those indications and uses, referred to as off-label uses, and our business, financial condition, results of operations, stock price and prospects will be materially harmed. We also must sufficiently substantiate any claims that we make for our products, including claims comparing our products to other companies' products, and must abide by the FDA's strict requirements regarding the content of promotion and advertising.

While physicians may choose to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, we are prohibited from marketing and promoting the products for indications and uses that are not specifically approved by the FDA. These off-label uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by biopharmaceutical companies concerning off-label use.

If we are found to have impermissibly promoted any of our product candidates, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations regarding product promotion, particularly those prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted a product may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

In the United States, engaging in the impermissible promotion of our products, following approval, for off-label uses can also subject us to false claims and other litigation under federal and state statutes. These include fraud and abuse and consumer protection laws, which can lead to civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which we promote or distribute therapeutic products and conduct our business. These restrictions could include corporate integrity agreements, suspension or exclusion from participation in federal and state healthcare programs, and suspension and debarment from government contracts and refusal of orders under existing government contracts. These False Claims Act lawsuits against manufacturers of drugs and biologics have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements, up to $3.0 billion, pertaining to certain sales practices and promoting off-label uses. In addition, False Claims Act lawsuits may expose manufacturers to follow-on claims by private payers based on fraudulent marketing practices. This growth in litigation has increased the risk that a biopharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid, or other federal and state healthcare programs. If we do not lawfully promote our approved products, if any, we may become subject to such litigation

and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

In the United States, the promotion of biopharmaceutical products is subject to additional FDA requirements and restrictions on promotional statements. If after one or more of our product candidates obtains marketing approval the FDA determines that our promotional activities violate its regulations and policies pertaining to product promotion, it could request that we modify our promotional materials or subject us to regulatory or other enforcement actions, including issuance of warning letters or untitled letters, suspension or withdrawal of an approved product from the market, requests for recalls, payment of civil fines, disgorgement of money, imposition of operating restrictions, injunctions or criminal prosecution, and other enforcement actions. Similarly, industry codes in foreign jurisdictions may prohibit companies from engaging in certain promotional activities and regulatory agencies in various countries may enforce violations of such codes with civil penalties. If we become subject to regulatory and enforcement actions our business, financial condition, results of operations, stock price and prospects will be materially harmed.

Even if our product candidates receive regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense and limit how we manufacture and market our products.

Any product candidate for which we obtain marketing approval will be subject to extensive and ongoing requirements of and review by the FDA and comparable foreign regulatory authorities, including requirements related to the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising, marketing, and promotional activities for such product. These requirements further include submissions of safety and other post-marketing information, including manufacturing deviations and reports, registration and listing requirements, the payment of annual fees, continued compliance with current Good Manufacturing Practice, or cGMP, requirements relating to manufacturing, quality control, quality assurance, and corresponding maintenance of records and documents, and good clinical practices, or GCPs, for any clinical trials that we conduct post-approval.

The FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may withdraw approval, issue public safety alerts, require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Any such restrictions could limit sales of the product.

We and any of our suppliers or collaborators, including our contract manufacturers, could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs and other FDA regulatory requirements. Application holders must further notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product and manufacturing changes.

In addition, later discovery of previously unknown adverse events or that the product is less effective than previously thought or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements both before and after approval, may yield various negative results, including:

- restrictions on manufacturing, distribution, or marketing of such products;
- restrictions on the labeling, including required additional warnings, such as black boxed warnings, contraindications, precautions, and restrictions on the approved indication or use;

- modifications to promotional pieces;
- issuance of corrective information;
- requirements to conduct post-marketing studies or other clinical trials;
- clinical holds or termination of clinical trials;
- requirements to establish or modify a REMS or similar strategy;
- changes to the way the product candidate is administered;
- liability for harm caused to patients or subjects;
- reputational harm;
- the product becoming less competitive;
- warning, untitled, or cyber letters;
- suspension of marketing or withdrawal of the products from the market;
- regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about the product candidate;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recalls of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure or detention;
- FDA debarment, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from federal healthcare programs, consent decrees, or corporate integrity agreements; or
- injunctions or the imposition of civil or criminal penalties, including imprisonment.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, or could substantially increase the costs and expenses of commercializing such product, which in turn could delay or prevent us from generating significant revenues from its marketing and sale. Any of these events could further have other material and adverse effects on our operations and business and could adversely impact our business, financial condition, results of operations, stock price and prospects.

The FDA's policies or those of comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates, limit the marketability of our product candidates, or impose additional regulatory obligations on us. Changes in medical practice and standard of care may also impact the marketability of our product candidates.

If we are slow or unable to adapt to changes in existing requirements, standards of care, or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and be subject to regulatory enforcement action.

Should any of the above actions take place, we could be prevented from or significantly delayed in achieving profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operations and business and could adversely impact our business, financial condition, results of operations, stock price and prospects.

Obtaining and maintaining marketing approval for our product candidates in one jurisdiction would not mean that we will be successful in obtaining marketing approval of that product candidate in other jurisdictions, which could prevent us from marketing our products internationally.

Obtaining and maintaining marketing approval of our product candidates in one jurisdiction would not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction, while a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the marketing approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable foreign regulatory authorities must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and, in some cases, greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. Additionally, the outcome of the United Kingdom's proposed withdrawal from the European Union remains uncertain. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the withdrawal of the United Kingdom from the European Union could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the European Union.

Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign marketing approvals and compliance with foreign regulatory requirements, including compliance with Brexit, could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of RP1 and our other product candidates will be harmed. If we obtain approval for any product candidate and ultimately commercialize that product in foreign markets, we would be subject to additional risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and the reduced protection of intellectual property rights in some foreign countries.

Risks related to commercialization

If we are unable to successfully commercialize any product candidate for which we receive regulatory approval, or experience significant delays in doing so, our business will be materially harmed.

If we are successful in obtaining marketing approval from applicable regulatory authorities for RP1 or any of our other product candidates, our ability to generate revenues from our product candidates will depend on our success in:

- launching commercial sales of our product candidates, whether alone or in collaboration with others;
- receiving an approved label with claims that are necessary or desirable for successful marketing, and that does not contain safety or other limitations that would impede our ability to market the product candidates;

- creating market demand for our product candidates through marketing, sales and promotion activities;
- hiring, training, and deploying a sales force or contracting with third parties to commercialize product candidates in the United States;
- manufacturing product candidates in sufficient quantities and at acceptable quality and cost to meet commercial demand at launch and thereafter;
- establishing and maintaining agreements with wholesalers, distributors, and group purchasing organizations on commercially reasonable terms;
- creating partnerships with, or offering licenses to, third parties to promote and sell product candidates in foreign markets where we receive marketing approval;
- maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- achieving market acceptance of our product candidates by patients, the medical community, and third-party payors;
- achieving appropriate reimbursement for our product candidates;
- effectively competing with other therapies; and
- maintaining a continued acceptable safety profile of our product candidates following launch.

To the extent we are not able to do any of the foregoing, our business, financial condition, results of operations, stock price and prospects will be materially harmed.

We face significant competition from other biopharmaceutical and biotechnology companies, academic institutions, government agencies, and other research organizations, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us. If their product candidates are shown to be safer or more effective than ours, our commercial opportunity may be reduced or eliminated.

The development and commercialization of cancer immunotherapy products is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary rights. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major biopharmaceutical companies, specialty biopharmaceutical companies, and biotechnology companies worldwide. There are a number of large biopharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of solid tumors, including oncolytic immunotherapy and cancer vaccine approaches. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

While our product candidates are intended to be used in combination with other drugs with different mechanisms of action, if and when marketed they will still compete with a number of drugs that are currently marketed or in development that also target cancer. To compete effectively with these drugs, our product candidates will need to demonstrate advantages in clinical efficacy and safety compared to these competitors when used alone or in combination with other drugs.

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are easier to administer or are less expensive alone or in combination with other therapies than any products that we may develop alone or in combination with other therapies. Our competitors also may obtain FDA

or comparable foreign regulatory authorities' approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors coverage decisions.

Many of the companies with which we are competing or may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the biopharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in developing or acquiring technologies complementary to, or necessary for, our programs. If we are unable to successfully compete with these companies our business, financial condition, results of operations, stock price and prospects may be materially harmed.

If we are unable to establish effective marketing, sales and distribution capabilities or enter into agreements with third parties to market and sell our product candidates, if they are approved, the revenues that we generate may be limited and we may never become profitable.

We currently do not have a commercial infrastructure for the marketing, sale, and distribution of our cancer immunotherapies. If and when our product candidates receive marketing approval, we intend to commercialize our product candidates on our own in the United States and potentially with pharmaceutical or biotechnology partners in other geographies. In order to commercialize our products, we must build our marketing, sales, and distribution capabilities or make arrangements with third parties to perform these services. We may not be successful in doing so. Should we decide to move forward in developing our own marketing capabilities, we may incur expenses prior to product launch or even approval in order to recruit a sales force and develop a marketing and sales infrastructure. If a commercial launch is delayed as a result of the FDA or comparable foreign regulatory authority requirements or other reasons, we would incur these expenses prior to being able to realize any revenue from sales of our product candidates. Even if we are able to effectively hire a sales force and develop a marketing and sales infrastructure, our sales force and marketing teams may not be successful in commercializing our product candidates. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We may also or alternatively decide to collaborate with third-party marketing and sales organizations to commercialize any approved product candidates in the United States, in which event, our ability to generate product revenues may be limited. To the extent we rely on third parties to commercialize any products for which we obtain regulatory approval, we may receive less revenues than if we commercialized these products ourselves, which could materially harm our prospects. In addition, we would have less control over the sales efforts of any other third parties involved in our commercialization efforts, and could be held liable if they failed to comply with applicable legal or regulatory requirements.

We have no prior experience in the marketing, sale, and distribution of biopharmaceutical products, and there are significant risks involved in building and managing a commercial infrastructure. The establishment and development of commercial capabilities, including compliance plans, to market any products we may develop will be expensive and time consuming and could delay any product launch, and we may not be able to successfully develop this capability. We will have to compete with other biopharmaceutical and biotechnology companies, including oncology-focused companies, to recruit, hire, train, manage, and retain marketing and sales personnel, which is expensive and time

consuming and could delay any product launch. Developing our sales capabilities may also divert resources and management attention away from product development.

In the event we are unable to develop a marketing and sales infrastructure, we may not be able to commercialize our product candidates in the United States or elsewhere, which could limit our ability to generate product revenues and materially harm our business, financial condition, results of operations, stock price and prospects. Factors that may inhibit our efforts to commercialize our product candidates include:

- the inability to recruit, train, manage, and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe our product candidates;
- our inability to effectively oversee a geographically dispersed sales and marketing team;
- the costs associated with training sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions;
- an inability to secure adequate coverage and reimbursement by government and private health plans;
- the clinical indications for which the products are approved and the claims that we may make for the products;
- limitations or warnings, including distribution or use restrictions, contained in the products' approved labeling;
- any distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities or to which we agree as part of a mandatory REMS or voluntary risk management plan;
- liability for sales or marketing personnel who fail to comply with the applicable legal and regulatory requirements;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization or engaging a contract sales organization.

Our product candidates are based on a novel approach to the treatment of cancer, which makes it difficult to predict the time and cost of product candidate development.

We have concentrated all of our research and development efforts on product candidates based on our Immulytic platform, and our future success depends on the successful development of this therapeutic approach. There can be no assurance that any development problems we experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be solved. Should we encounter development problems, including unfavorable preclinical or clinical trial results, the FDA and foreign regulatory authorities may refuse to approve our product candidates, or may require additional information, tests, or trials, which could significantly delay product development and significantly increase our development costs. Moreover, even if we are able to provide the requested information or trials to the FDA, there would be no guarantee that the FDA would accept them or approve our product candidates. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process, or developing or qualifying and validating product release assays, other testing and manufacturing methods, and our equipment and facilities in a timely

manner, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all.

In addition, the clinical trial requirements of the FDA and comparable foreign regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The FDA and comparable foreign regulatory authorities have limited experience with the approval of oncolytic immunotherapies. Only one oncolytic immunotherapy, T-Vec, has received FDA approval to date. Any product candidates that are approved may be subject to extensive post-approval regulatory requirements, including requirements pertaining to manufacturing, distribution, and promotion. We may need to devote significant time and resources to compliance with these requirements.

If our product candidates do not achieve broad market acceptance, the revenues that we generate from their sales may be limited, and we may never become profitable.

We have never commercialized a product candidate for any indication. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors, and others in the medical community. If any product candidates for which we obtain regulatory approval do not gain an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. Market acceptance of our product candidates by the medical community, patients, and third-party payors will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients and patients may be reluctant to switch from existing therapies even when new and potentially more effective or safer treatments enter the market.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates is approved but does not achieve an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. The degree of market acceptance of any of our product candidates will depend on a number of factors, including:

- the efficacy of our product candidates in combination with marketed checkpoint blockade drugs;
- the commercial success of the checkpoint blockade drugs with which our products are co-administered;
- the prevalence and severity of adverse events associated with our product candidates or those products with which they are co-administered;
- the clinical indications for which the products are approved and the approved claims that we may make for the products;
- limitations or warnings contained in the product's FDA-approved labeling or those of comparable foreign regulatory authorities, including potential limitations or warnings for our product candidates that may be more restrictive than other competitive products;
- changes in the standard of care for the targeted indications for our product candidates, which could reduce the marketing impact of any claims that we could make following FDA approval or approval by comparable foreign regulatory authorities, if obtained;
- the relative convenience and ease of administration of our product candidates by direct injection into tumors, a less common method for the administration of oncology therapies than systemic administration, which may result in slower adoption of our therapies;
- the relative convenience and ease of administration of any products with which our product candidates are co-administered

- the cost of treatment compared with the economic and clinical benefit of alternative treatments or therapies;
- the availability of adequate coverage or reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid;
- the price concessions required by third-party payors to obtain coverage;
- the extent and strength of our marketing and distribution of our product candidates;
- the safety, efficacy, and other potential advantages over, and availability of, alternative treatments already used or that may later be approved;
- distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities with respect to our product candidates or to which we agree as part of a REMS or voluntary risk management plan;
- the timing of market introduction of our product candidates, as well as competitive products;
- our ability to offer our product candidates for sale at competitive prices;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the extent and strength of our third-party manufacturer and supplier support;
- the actions of companies that market any products with which our product candidates are co-administered;
- the approval of other new products;
- adverse publicity about our product candidates or any products with which they are co-administered, or favorable publicity about competitive products; and
- potential product liability claims.

The size of the potential market for our product candidates is difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our product candidates may be smaller than our estimates.

The potential market opportunities for our product candidates are difficult to estimate and will depend in large part on the drugs with which our product candidates are co-administered and the success of competing therapies and therapeutic approaches. In particular, the market opportunity for oncolytic immunotherapies is hard to estimate given that it is an emerging field with only one existing FDA-approved oncolytic immunotherapy, T-Vec, which has yet to enjoy broad market acceptance. Our estimates of the potential market opportunities are predicated on many assumptions, which may include industry knowledge and publications, third-party research reports, and other surveys. Although we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain, and their reasonableness has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities.

Negative developments in the field of immuno-oncology could damage public perception of RP1 or any of our other product candidates and negatively affect our business.

The commercial success of our product candidates will depend in part on public acceptance of the use of cancer immunotherapies. Adverse events in clinical trials of RP1 or our other product candidates or in clinical trials of others developing similar products and the resulting publicity, as well as any other negative developments in the field of immuno-oncology that may occur in the future, including in

connection with competitor therapies, could result in a decrease in demand for RP1 or our other product candidates that we may develop. These events could also result in the suspension, discontinuation, or clinical hold of or modification to our clinical trials. If public perception is influenced by claims that the use of cancer immunotherapies is unsafe, whether related to our therapies or those of our competitors, our product candidates may not be accepted by the general public or the medical community and potential clinical trial subjects may be discouraged from enrolling in our clinical trials. As a result, we may not be able to continue or may be delayed in conducting our development programs.

As our product candidates consist of a modified virus, adverse developments in anti-viral vaccines or clinical trials of other oncolytic immunotherapy products based on viruses may result in a disproportionately negative effect for RP1 or our other product candidates as compared to other products in the field of immuno-oncology that are not based on viruses. Future negative developments in the field of immuno-oncology or the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our products. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for RP1 or our other product candidates.

Risks related to our financial position and need for additional capital

We are a clinical-stage biopharmaceutical company with a very limited operating history. We have incurred net losses since our inception and anticipate that we will continue to incur substantial and increasing net losses in the foreseeable future. We may never achieve or sustain profitability.

We are a clinical-stage biopharmaceutical company with a limited operating history, and we are early in our development efforts. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain marketing approval and become commercially viable. We have financed our operations to date primarily through the sale of equity securities, including the sale of our common stock in our IPO. Since our inception, most of our resources have been dedicated to the preclinical and clinical development of our Immulytic platform, RP1 and our other product candidates. The size of our future net losses will depend, in part, on our future expenses and our ability to generate revenue, if any.

We are not profitable and have incurred losses in each period since our inception. For the years ended March 31, 2019, 2018 and 2017, we reported a net loss of $30.8 million, $19.7 million and $7.7 million, respectively. At March 31, 2019, we had an accumulated deficit of $59.8 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek marketing approvals for, RP1 and any additional product candidates we may develop.

Even if we succeed in receiving marketing approval for and commercialize RP1, we will continue to incur substantial research and development and other expenditures to develop and market additional potential products. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We have never generated any revenue from product sales, and our ability to generate revenue from product sales and become profitable will depend significantly on our success in achieving a number of goals.

We have no products approved for commercial sale, have not generated any revenue from product sales, and do not anticipate generating any revenue from product sales until after we have received marketing approval for the commercial sale of a product candidate, if ever. Our ability to generate revenue and achieve profitability depends significantly on our success in achieving a number of goals, including:

- completing research regarding, and preclinical and clinical development of, RP1 and our other product candidates;
- obtaining marketing approvals for RP1 and our other product candidates for which we complete clinical trials;
- developing a sustainable and scalable manufacturing process for RP1 and our other product candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third parties;
- launching and commercializing RP1 and our other product candidates for which we obtain marketing approvals, either directly or with a collaborator or distributor;
- obtaining market acceptance of RP1 and our other product candidates as viable treatment options;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and developing new product candidates;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- obtaining, maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and
- attracting, hiring, and retaining qualified personnel.

Even if our product candidates or any future product candidates that we develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any such product candidate. Our expenses could increase beyond expectations if we are required by the FDA or comparable foreign regulatory authorities to change our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of studies in addition to those that we currently anticipate.

If we are successful in obtaining regulatory approvals to market RP1 or our other product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain marketing approval, the accepted price for the product, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, the labels for our product candidates contain significant safety warnings, regulatory authorities impose burdensome or restrictive distribution requirements, or the reasonably accepted patient population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate revenue from the sale of any approved products, we could be prevented from or significantly delayed in achieving profitability.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

Our operations have consumed substantial amounts of cash since inception. At March 31, 2019, our cash and cash equivalents and short-term investments were $134.8 million We expect to continue to spend substantial amounts to continue the clinical and preclinical development of RP1 and our other product candidates. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives. If we are able to gain marketing approval of any product candidate, we will require significant additional amounts of cash in order to launch and commercialize such product. In addition, other unanticipated costs may arise.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing RP1 and our other product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining marketing approvals for RP1 and our other product candidates if clinical trials are successful;
- the success of any collaborations;
- the cost of commercialization activities for any approved product, including marketing, sales and distribution costs;
- the cost and timing of establishing, equipping, and operating our planned manufacturing facility;
- the cost of manufacturing RP1 and our other product candidates for clinical trials in preparation for marketing approval and commercialization;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the timing, receipt, and amount of sales of, or royalties on, our future products, if any; and
- the emergence of competing cancer therapies and other adverse market developments.

We do not have any committed external source of funds or other support for our development efforts. Until we can generate sufficient product revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. Based on our research and development plans, we expect that our existing cash and cash equivalents and short-term investments will enable us to fund our planned operating expenses and capital expenditure requirements into the second half of calendar year 2021. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. In addition, because the design and outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of RP1 or our other product candidates.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, our existing stockholders' interest will be diluted. Debt

financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we are unable to raise additional funds through equity or debt financings when needed, we may be required to grant rights to develop and market one or more of our product candidates or technologies that we would otherwise prefer to develop and market ourselves.

Risks related to intellectual property

If we are unable to obtain, maintain and protect our intellectual property rights for our technology and product candidates, or if our intellectual property rights are inadequate, our competitive position could be harmed.

Our commercial success will depend in part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our technology, Immulytic platform, RP1 and our other product candidates. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. We seek to protect our proprietary position by filing and prosecuting patent applications in the United States and abroad related to our technology and product candidates.

The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our licensed patents and any patents we own in the future are highly uncertain. The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside of the United States.

Further, the examination process may require us to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The scope of a patent may also be reinterpreted after issuance. The rights that may be granted under our future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we are unable to obtain and maintain patent protection for our technology or for RP1 or our other product candidates, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize products similar or superior to ours, and our ability to successfully commercialize RP1 or our other product candidates and future technologies may be adversely affected. It is also possible that we will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them.

In addition, the patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. It is also possible that we will fail to identify patentable aspects of our research and development efforts in time to obtain patent protection.

For the core technology in our Immulytic platform and each of our product candidates, we have filed five patent applications under the Patent Cooperation Treaty, or PCT, and four U.S. provisional applications. Four of these PCT applications have entered the national phase and are pending in a

range of countries, and one is still in the international phase. None of our PCT-derived patent applications or U.S. provisional applications have been granted by a patent office. Early stage examination has started only in connection with the European national phase applications. Any future provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of filing of one or more of our related provisional patent applications. If we do not timely file any non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. Although we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any of our future patent applications will result in the issuance of patents that effectively protect our technology or RP1 or our other product candidates, or if any of our future issued patents will effectively prevent others from commercializing competitive products. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all until they are issued as a patent. Therefore, we cannot be certain that we were the first to make the inventions claimed in our pending patent applications, or that we were the first to file for patent protection of such inventions.

Our pending applications cannot be enforced against third parties practicing the inventions claimed in such applications unless and until a patent issues from such applications. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we license from third parties or own in the future may be challenged in the courts or patent offices in the United States and abroad, including through opposition proceedings, derivation proceedings, *inter partes* review, interference proceedings or litigation. Such proceedings may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical products, or limit the duration of the patent protection for our technology. Protecting against the unauthorized use of our patented inventions, trademarks and other intellectual property rights is expensive, time consuming, difficult and in some cases may not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult. If we are unable to obtain, maintain, and protect our intellectual property our competitive advantage could be harmed, and it could result in a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to seeking patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how and confidential and proprietary information. To maintain the confidentiality of our trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants, collaborators and other third parties who have access to our trade secrets. Our agreements with employees also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. In addition, in the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in

their work for us, disputes may arise between us and those third parties as to the rights in related inventions.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information including a breach of our confidentiality agreements. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time consuming, and the outcome is unpredictable. In addition, some courts in and outside of the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. The disclosure of our trade secrets or the independent development of our trade secrets by a competitor or other third party would impair our competitive position and may materially harm our business, financial condition, results of operations, stock price and prospects.

Third parties may in the future initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could harm our business.

Our commercial success depends on our ability and the ability of our current or future collaborators to develop, manufacture, market and sell RP1 and our other product candidates, and to use our related proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any other future product candidates, including interference proceedings, post-grant review, *inter partes* review and derivation proceedings before the U.S. Patent and Trademark Office, or USPTO. Third parties may assert infringement or other intellectual property claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, and we are unsuccessful in demonstrating that such intellectual property rights are invalid or unenforceable, we could be required to obtain a license from such third party to continue developing, manufacturing and commercializing RP1 and our other product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We also could be forced, including by court order, to cease developing, manufacturing, and commercializing RP1 or our other product candidates. In addition, in any such proceeding or litigation, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar material adverse effect on our business.

In addition, we are developing RP1 in combination with nivolumab and cemiplimab, which are covered by patents or licenses held by BMS and Regeneron, respectively, to which we do not have a license other than for use in connection with the applicable clinical trial. We also plan to develop our product candidates in combination with products developed by additional companies that are covered by patents or licenses held by those entities to which we do not have a license. In the event that a labeling instruction is required in product packaging recommending that combination, we could be accused of, or held liable for, infringement of the third-party patents covering the product candidate or product recommended for administration with RP1 or our other product candidates. In such a case, we could be required to obtain a license from the other company or institution to use the required or desired package labeling, which may not be available on commercially reasonable terms, or at all.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting and defending patents on our technology in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws and practices of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop and/or manufacture their own products and may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the granting or enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to obtain patent rights or stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally in those countries. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to protect and enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property we develop or license.

In addition, the laws of certain foreign countries may not protect our rights to the same extent as the laws of the United States, and those foreign laws may also be subject to change. For example, methods of treatment and manufacturing processes may not be patentable in certain jurisdictions, and the requirements for patentability may differ in certain countries. Furthermore, biosimilar product manufacturers or other competitors may challenge the scope, validity and enforceability of our patents, requiring us to engage in complex, lengthy and costly litigation or proceedings.

Moreover, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. Many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business and results of operations may be adversely affected.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payments and other similar provisions during the patent application process and to maintain patents after they are issued. For example, periodic maintenance fees, renewal fees, annuity fees and various other government fees on issued patents and patent applications often must be paid to the USPTO and foreign patent agencies over the lifetime of our licensed patents or

any patents we own in the future. In certain circumstances, we may rely on future licensing partners to take the necessary action to comply with these requirements with respect to licensed intellectual property. Although an unintentional lapse can be cured for a period of time by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to obtain and maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to RP1 or our other product candidates, which could have a material adverse effect on our business.

Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect RP1 and our other product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business.

Competitors may infringe any future licensed patents or any patent we own in the future or misappropriate or otherwise violate our intellectual property rights. We may also be required to defend against claims of infringement and our licensed patents and any patents we own in the future may become involved in priority or other intellectual property related disputes. To counter infringement or

unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Also, third parties may initiate legal proceedings against us to assert that we are infringing their intellectual property rights or to challenge the validity or scope of our owned or licensed intellectual property rights. These proceedings can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to conduct intellectual property related litigations or proceedings than we can. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation and other intellectual property related proceedings could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or other intellectual property related proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation in the United States, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments in any such proceedings. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Any of the foregoing may have a material adverse effect our business, financial condition, results of operations, stock price and prospects.

We may be subject to claims by third parties asserting that our collaborators, employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management team, were previously employed at, or consulted for, universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Our collaborators' employees may currently be or previously have been employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these persons, including each member of our senior management team, executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment or consulting agreements, that assigned ownership of intellectual property relating to work performed under such agreements to the contracting third party. Although we take steps to ensure that our employees do not use, claim as theirs, or misappropriate the intellectual property, proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used, claimed as theirs, misappropriated or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms, or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed confidential information of third parties or are in breach of non-competition or non-solicitation agreements with our competitors.

We could be subject to claims that we or our employees, including senior management, have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors or others. Although we take steps to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we caused an employee to breach the terms of their non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor or other party. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to RP1 and our other product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers, competitors or other parties. An inability to incorporate such technologies or features would have a material adverse effect on our business, and may prevent us from successfully commercializing RP1 and our other product candidates. In addition, we may lose valuable intellectual property rights or personnel as a result of such claims. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or consultants. A loss of key personnel or their work product could hamper or prevent our ability to develop and commercialize RP1 and our other product candidates, which could have an adverse effect on our business, financial condition, results of operations, stock price and prospects.

If we obtain any issued patents covering our technology, such patents could be found invalid or unenforceable if challenged in court or before the USPTO or comparable foreign regulatory authority.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering any of our technology, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be, among other things, an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be, among other things, an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post-grant review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions, such as opposition proceedings. Such proceedings could result in revocation, cancellation or amendment of our patents in such a way that they no longer cover and protect RP1 and our other product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. For example, with respect to the validity of our licensed patents or any patents we obtain in the future, we cannot be certain that there is no invalidating prior art of which we, our or our licensing partner's patent counsel, and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on RP1 and our other product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time, and our product candidates for which we intend to seek approval as biological products may face competition sooner than anticipated.

Given the amount of time required for the development, testing and regulatory review of new product candidates, such as RP1 and our other product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, but no longer than 14 years from the product's approval date, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authorities in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their products earlier than might otherwise be the case, which could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

The enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, as part of the Patient Protection and Affordable Care Act, or ACA, created an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. Certain changes, however, and supplements to an approved BLA, and subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest, or other related entity do not qualify for the 12-year exclusivity period.

RP1 and our other product candidates are all biological product candidates. We anticipate being awarded market exclusivity for each of our biological product candidates that is subject to its own BLA for 12 years in the United States, 10 years in Europe and significant durations in other markets. However, the term of the patents that cover such product candidates may not extend beyond the applicable market exclusivity awarded by a particular country. For example, in the United States, if all of the patents that cover our particular biological product expire before the 12-year market exclusivity expires, a third party could submit a marketing application for a biosimilar product four years after approval of our biological product, the FDA could immediately review the application and approve the biosimilar product for marketing 12 years after approval of our biological product, and the biosimilar sponsor could then immediately begin marketing. Alternatively, a third party could submit a full BLA for a similar or identical product any time after approval of our biological product, and the FDA could immediately review and approve the similar or identical product for marketing and the third party could begin marketing the similar or identical product upon expiry of all of the patents that cover our particular biological product.

There is also a risk that this exclusivity could be changed in the future. For example, this exclusivity could be shortened due to congressional action or through other actions, including future proposed budgets, international trade agreements and other arrangements or proposals. Additionally, there is a risk that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. The extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. It is also possible that payers will give reimbursement preference to biosimilars over reference biologics, even absent a determination of interchangeability.

To the extent that we do not receive any anticipated periods of regulatory exclusivity for our product candidates or the FDA or foreign regulatory authorities approve any biosimilar, interchangeable, or other competing products to our product candidates, it could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

Risks related to manufacturing and our reliance on third parties

We have agreements with BMS and Regeneron, and in the future may have agreements with other companies, to obtain the supply of anti-PD-1 therapies for the development of RP1 and our other product candidates. If our relationships with BMS, Regeneron, or any future collaborator or supplier are not successful, we may be delayed in completing the development of RP1 and our other product candidates.

We have entered into arrangements with BMS and Regeneron as part of our clinical development for RP1. BMS is providing nivolumab, its anti-PD-1 therapy, for use in our ongoing Phase 1/2 clinical trial with RP1 and Regeneron is providing cemiplimab, its anti-PD-1 therapy, for use in our randomized, controlled Phase 2 clinical trial with RP1 in approximately 240 patients with CSCC and other potential clinical trials. We may also enter into agreements with additional companies for the supply of anti-PD-1 therapies for use in the development of RP1 and our other product candidates. The outcome of these clinical trials is dependent both on the performance of our partners' products and product candidates and also on our partners' ability to deliver sufficient quantities of adequately produced product. Should any of our partners' products or product candidates fail to produce the results that we anticipate, we may have to rerun clinical trials for RP1 or our other product candidates or may otherwise be delayed in the commercialization of RP1 or our other product candidates. Similarly, should any partner fail to provide us with a product or product candidate that suits our requirements we may have to rerun clinical trials for RP1 or our other product candidates or may be otherwise delayed in the commercialization of RP1 or our other product candidates.

Our collaboration agreements with any future partners may not be successful, which could adversely affect our ability to develop and commercialize our product candidates.

We may in the future seek collaboration arrangements with other parties for the development or commercialization of our product candidates. The success of any collaboration arrangements may depend on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these arrangements. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority.

Collaborations with biopharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration could adversely affect us financially and could harm our business reputation.

Any future collaborations we might enter into may pose a number of risks, including the following:

- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could fail to make timely regulatory submissions for a product candidate;
- collaborators may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements, which could subject them or us to regulatory enforcement actions;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product candidate or product;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; and
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability.

If any collaborations we might enter into in the future do not result in the successful development and commercialization of products or if one of our collaborators subsequently terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such potential future collaboration. If we do not receive the funding we expect under the agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates and our product platform.

Additionally, if any future collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate development or commercialization of any product candidate it licenses to us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our reputation in the business and financial communities could be adversely affected.

We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its

development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our product platform and our business may be materially and adversely affected.

We rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials. If those third parties do not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with regulatory requirements, we may be unable to obtain regulatory approval for our product candidates or any other product candidates that we may develop in the future.

We rely on third-party CROs, study sites, and others to conduct, supervise, and monitor our preclinical studies and clinical trials for our product candidates and do not currently plan to independently conduct preclinical studies or clinical trials of any other potential product candidates. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our preclinical studies and clinical trials. Although we have agreements governing their activities, we have limited influence over their actual performance and control only certain aspects of their activities. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we may be delayed in completing or unable to complete the studies required to support future approval of our product candidates, or we may not obtain marketing approval for or commercialize our product candidates in a timely manner or at all. Moreover, these agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements our product development activities would be delayed and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our trials is conducted in accordance with the general investigational plan and protocols for the trial. We must also ensure that our preclinical trials are conducted in accordance with the FDA's Good Laboratory Practice, or GLP, regulations, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with standards, commonly referred to as GCPs for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators, and trial sites. If we or any of our third parties fail to comply with applicable GCPs or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the data generated in our trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional studies.

In addition, we will be required to report certain financial interests of our third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who may have conflicts of interest.

We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our trials complies with the applicable regulatory requirements. In addition, our clinical trials must be conducted with product candidates that were produced under cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register certain clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in enforcement actions and adverse publicity.

The third parties with which we work may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting trials or other therapeutic development activities that could harm our competitive position. In addition, such third parties are not our employees, and except for remedies available to us under our agreements with such third parties we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, non-clinical, and preclinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our trials may be repeated, extended, delayed, or terminated; we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates; we may not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates, or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative providers or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines.

We also rely on other third parties to store and distribute our products for the clinical trials that we conduct. Any performance failure on the part of our distributors could delay clinical development, marketing approval, or commercialization of our product candidates, which could result in additional losses and deprive us of potential product revenue.

If the manufacturers upon which we rely fail to produce our product candidates in the volumes that we require on a timely basis, or fail to comply with stringent regulations applicable to biopharmaceutical manufacturers, we may face delays in the development and commercialization of, or be unable to meet demand for, our product candidates and may lose potential revenues.

Until our planned manufacturing facility is operational, we will continue to rely on third-party contract manufacturers to manufacture our clinical trial product supplies. There can be no assurance that our clinical development will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices. In particular, any replacement of our contract manufacturer could require significant effort and expertise because there may be a limited number of qualified replacements. Any delays in obtaining adequate supplies of our product candidates that meet the necessary quality standards may delay our development or commercialization.

We may not succeed in our efforts to establish manufacturing relationships or other alternative arrangements for any of our product candidates or programs. Our product candidates may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing and filling our viral product for us and willing to do so. If our existing third-party manufacturers, or the third parties that we engage in the future, should cease to work with us, we likely would experience delays in obtaining sufficient quantities of our product candidates for us to meet commercial demand or to advance our clinical trials while we identify and qualify replacement suppliers. If for any reason we are unable to obtain adequate supplies of our product candidates or the therapeutic substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively. Further, even if we do establish such collaborations or arrangements, our third-party manufacturers may breach, terminate, or not renew these agreements.

Any problems or delays we experience in preparing for commercial-scale manufacturing of a product candidate or component may result in a delay in product development timelines and FDA or comparable foreign regulatory authority approval of the product candidate or may impair our ability to manufacture commercial quantities or such quantities at an acceptable cost and quality, which could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates and may materially harm our business, financial condition, results of operations, stock price and prospects.

We currently have only one contract manufacturer for our product candidates for use in our clinical trials. In addition, we do not have any long-term commitments from our suppliers of clinical trial material or guaranteed prices for our product candidates or their components. The manufacture of biopharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of therapeutics often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel or key raw materials, and compliance with strictly enforced federal, state, and foreign regulations. Our contract manufacturers may not perform as agreed. If our manufacturers were to encounter these or other difficulties, our ability to provide product candidates to patients in our clinical trials could be jeopardized.

Contract manufacturers of our product candidates may be unable to comply with our specifications, applicable cGMP requirements or other FDA, state or foreign regulatory requirements. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of a product candidate that may not be detectable in final product testing. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. Any such deviations may also require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. Any delays in obtaining products or product candidates that comply with the applicable regulatory requirements may result in delays to clinical trials, product approvals, and commercialization. It may also require that we conduct additional studies.

While we are ultimately responsible for the manufacturing of our product candidates and therapeutic substances, other than through our contractual arrangements, we have little control over our manufacturers' compliance with these regulations and standards. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product

candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Any new manufacturers would need to either obtain or develop the necessary manufacturing know-how, and obtain the necessary equipment and materials, which may take substantial time and investment. We must also receive FDA approval for the use of any new manufacturers for commercial supply.

A failure to comply with the applicable regulatory requirements, including periodic regulatory inspections, may result in regulatory enforcement actions against our manufacturers or us (including fines and civil and criminal penalties, including imprisonment) suspension or restrictions of production, injunctions, delay or denial of product approval or supplements to approved products, clinical holds or termination of clinical trials, warning or untitled letters, regulatory authority communications warning the public about safety issues with the product candidate, refusal to permit the import or export of the products, product seizure, detention, or recall, operating restrictions, suits under the civil False Claims Act, corporate integrity agreements, consent decrees, withdrawal of product approval, environmental or safety incidents and other liabilities. If the safety of any quantities supplied is compromised due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

Any failure or refusal to supply our product candidates or components for our product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

If there are delays in completing our planned manufacturing facility, we may be delayed in scaling up manufacturing of our product candidates, may be forced to devote additional resources and management time to completing our manufacturing facility and may face delays in our product development timelines. Additionally, the transition of our manufacturing operations to our new facility may result in further delays or expenses, and we may not experience the anticipated operating efficiencies.

We have begun construction activities with respect to a lease signed in June 2018 for an approximately 63,000 square-foot facility in Framingham, Massachusetts at which we intend to establish and equip our own manufacturing facility in order to secure supplies for pivotal studies and commercial launch. This facility is intended to give us control over key aspects of the supply chain for our products and product candidates. We may face delays in the completion of the facility. In addition, we may not experience the anticipated operating efficiencies as we commence manufacturing operations at the new facility. Any such delays may disrupt or delay the supply of our product candidates if we have not maintained a sufficient back-up supply of our product candidates through third-party manufacturers. Moreover, changing manufacturing facilities may also require that we conduct additional studies, make notifications to the regulatory authorities, make additional filings to the regulatory authorities, and obtain regulatory authority approval for the new facilities, which may be delayed or which we may never receive. We will further need to comply with the FDA's and applicable foreign regulatory authorities' cGMP requirements for the production of our product candidates for clinical trials and, if approved, commercial supply, and will be subject to FDA and comparable foreign regulatory authority inspection. These requirements include the qualification and validation of our manufacturing equipment and processes. We may not be able to develop or acquire the internal expertise and resources necessary for compliance with these requirements. Should we fail to comply with cGMP regulations, the opening of our manufacturing facility will be delayed. If we fail to achieve the operating efficiencies that we anticipate, our manufacturing and operating costs may be greater than expected, which could have a material adverse impact on our operating results.

In order to complete our planned manufacturing facility, we may be forced to devote greater resources and management time than anticipated, particularly in areas relating to operations, quality, regulatory, facilities and information technology. If we experience unanticipated employee turnover in any of these areas, we may not be able to effectively manage our ongoing manufacturing operations and we may not achieve the operating efficiencies that we anticipate from the new facility, which may negatively affect our product development timeline.

Any such problems could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates and may materially harm our business, financial condition, results of operations, stock price and prospects.

Risks related to legal and compliance matters

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability and have to limit the commercialization of any approved products and/or our product candidates.

The use of our product candidates in clinical trials, and the sale of any product for which we obtain regulatory approval, exposes us to the risk of product liability claims. We face inherent risk of product liability related to the testing of our product candidates in human clinical trials, including liability relating to the actions and negligence of our investigators, and will face an even greater risk if we commercially sell any product candidates that we may develop. For example, we may be sued if any product candidate we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. Product liability claims might be brought against us by consumers, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of merit or eventual outcome, liability claims may result in:

- loss of revenue from decreased demand for our products and/or product candidates;
- impairment of our business reputation or financial stability;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- diversion of management attention;
- withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs;
- the inability to commercialize our product candidates;
- significant negative media attention;
- decreases in our stock price;
- initiation of investigations and enforcement actions by regulators; and
- product recalls, withdrawals or labeling, marketing or promotional restrictions, including withdrawal of marketing approval.

We believe we have sufficient insurance coverage in place for our business operations. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain FDA or comparable foreign regulatory approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing, or at all. Failure to obtain and retain sufficient product liability insurance at an acceptable cost could prevent or inhibit the commercialization of products we develop. On occasion, large judgments have been awarded in class action lawsuits based on therapeutics that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash, and materially harm our business, financial condition, results of operations, stock price and prospects.

We are subject to the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act and other anti-corruption laws, as well as import and export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures, and legal expenses, which could adversely affect our business, financial condition, results of operations, stock price and prospects.

Our operations are subject to anti-corruption laws, including the U.S. Foreign Corrupt Practices Act, or FCPA, the U.K. Bribery Act 2010, or the Bribery Act, and other anti-corruption laws that apply in countries where we do business. The FCPA, the Bribery Act, and these other laws generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We also may participate in collaborations and relationships with third parties whose actions, if non-compliant, could potentially subject us to liability under the FCPA, Bribery Act or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United States and the United Kingdom and authorities in the European Union, including applicable import and export control regulations, economic sanctions on countries and persons, anti-money laundering laws, customs requirements and currency exchange regulations, collectively referred to as the trade control laws.

We can provide no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws or other legal requirements, including trade control laws. If we are not in compliance with applicable anti-corruption laws or trade control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations, stock price and prospects. Likewise, any investigation of any potential violations of these anti-corruption laws or trade control laws by U.S., U.K. or other authorities could also have an adverse impact on our reputation, our business, financial condition, results of operations, stock price and prospects.

If we fail to comply with federal and state healthcare laws, including fraud and abuse and health and other information privacy and security laws, we could face substantial penalties and our business, financial condition, results of operations, stock price and prospects will be materially harmed.

We are subject to many federal and state healthcare laws, including those described in "Business—Regulatory matters," such as the federal Anti-Kickback Statute, the federal civil and criminal False Claims Acts, the civil monetary penalties statute, the Medicaid Drug Rebate statute and other price reporting requirements, the Veterans Health Care Act of 1992, or VHCA, the federal Health Insurance Portability and Accountability Act of 1996 (as amended by the Health Information Technology for Economics and Clinical Health Act, or HITECH), or HIPAA, the FCPA, the ACA, and similar state laws. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws, and regulations pertaining to fraud and abuse, reimbursement programs, government procurement, and patients' rights are and will be applicable to our business. We would be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business. In the European Union, the data privacy laws are generally stricter than those that apply in the United States and include specific requirements for the collection of personal data of European Union persons or the transfer of personal data outside of the European Union to the United States to ensure that European Union standards of data privacy will be applied to such data.

If we or our operations are found to be in violation of any federal or state healthcare law, or any other governmental laws or regulations that apply to us, we may be subject to penalties, including civil, criminal, and administrative penalties, damages, fines, disgorgement, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from participation in U.S. federal or state health care programs, corporate integrity agreements, and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including but not limited to, exclusions from participation in government healthcare programs, which could also materially affect our business.

Although an effective compliance program can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with applicable federal, state and foreign privacy, data protection, security, reimbursement, and fraud laws may prove costly. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

If the government or third-party payors fail to provide adequate coverage, reimbursement and payment rates for our product candidates, or if health maintenance organizations or long-term care facilities choose to use therapies that are less expensive or considered a better value, our revenue and prospects for profitability will be limited.

In both domestic and foreign markets, sales of our products will depend in part upon the availability of coverage and reimbursement from third-party payors. Such third-party payors include government health programs such as Medicare and Medicaid, managed care providers, private health insurers, and other organizations. Coverage decisions may depend upon clinical and economic standards that disfavor new therapeutic products when more established or lower cost therapeutic alternatives are already available or subsequently become available, even if our products are alone in a class. If reimbursement is not available, or is available only to limited levels, our product candidates may be competitively disadvantaged, and we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough

to allow us to establish or maintain a market share sufficient to realize a sufficient return on our or their investments. Alternatively, securing favorable reimbursement terms may require us to compromise pricing and prevent us from realizing an adequate margin over cost.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved therapeutics. Marketing approvals, pricing, and reimbursement for new therapeutic products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a therapeutic before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription biopharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. Our ability to commercialize our product candidates will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Regulatory authorities and third-party payors, such as private health insurers, and health maintenance organizations, decide which medications they will cover and establish reimbursement levels. The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Several third-party payors are requiring that companies provide them with predetermined discounts from list prices, are using preferred drug lists to leverage greater discounts in competitive classes, are disregarding therapeutic differentiators within classes, are challenging the prices charged for therapeutics, and are negotiating price concessions based on performance goals.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for our products or product candidates for which we receive regulatory approval may not be available or adequate in either the United States or international markets, which could have a negative effect on our business, financial condition, results of operations, stock price and prospects.

Assuming coverage is approved, the resulting reimbursement payment rates might not be adequate. If payors subject our product candidates to maximum payment amounts, or impose limitations that make it difficult to obtain reimbursement, providers may choose to use therapies which are less expensive when compared to our product candidates. Additionally, if payors require high copayments, beneficiaries may seek alternative therapies. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any products to the satisfaction of hospitals, other target customers and their third-party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Our products might not ultimately be considered cost-effective. Adequate third-party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

In addition, federal programs impose penalties on manufacturers of therapeutics in the form of mandatory additional rebates and/or discounts if commercial prices increase at a rate greater than the Consumer Price Index-Urban, and these rebates and/or discounts, which can be substantial, may impact our ability to raise commercial prices. A few states have also passed or are considering legislation intended to prevent significant price increases. Regulatory authorities and third-party payors have

attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability to sell our product candidates profitably. These payors may not view our products, if any, as cost-effective, and coverage and reimbursement may not be available to our customers, or may not be sufficient to allow our products, if any, to be marketed on a competitive basis. Cost-control initiatives could cause us to decrease, discount, or rebate a portion of the price we, or they, might establish for products, which could result in lower than anticipated product revenues. If the realized prices for our products, if any, decrease or if governmental and other third-party payors do not provide adequate coverage or reimbursement, our prospects for revenue and profitability will suffer.

There may also be delays in obtaining coverage and reimbursement for newly approved therapeutics, and coverage may be more limited than the indications for which the product is approved by the FDA or comparable foreign regulatory authorities. Such delays have made it increasingly common for manufacturers to provide newly approved drugs to patients experiencing coverage delays or disruption at no cost for a limited period in order to ensure that patients are able to access the drug. Moreover, eligibility for reimbursement does not imply that any therapeutic will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new therapeutics, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary, by way of example, according to the use of the product and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost products or may be incorporated into existing payments for other services.

In addition, third-party payors are increasingly requiring higher levels of evidence of the benefits and clinical outcomes of new technologies, benchmarking against other therapies, seeking performance-based discounts, and challenging the prices charged. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if available, that the reimbursement rates will be adequate. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any of our product candidates for which we obtain marketing approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

We are subject to new legislation, regulatory proposals and healthcare payor initiatives that may increase our costs of compliance, and adversely affect our ability to market our products, obtain collaborators, and raise capital.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved products.

For example, legislative changes have been proposed and adopted since the ACA was enacted in 2010. These changes include, among other things, aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went effective on April 1, 2013. In addition, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Centers for Medicare and Medicaid Services, or CMS, promulgated regulations governing manufacturers' obligations and reimbursement under the Medicaid Drug Rebate Program, and recently promulgated a regulation that limited Medicare Part B payment to certain hospitals for outpatient drugs purchased under the 340B program. Changes imposed by recent

legislative actions are further described in "Business—Regulatory matters." These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our products, if approved, and, accordingly, on our results of operations.

We expect that the ACA, as well as other federal and state healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria, increased regulatory burdens and operating costs, decreased net revenue from our biopharmaceutical products, decreased potential returns from our development efforts, and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from commercializing our products and being able to generate revenue, and we could be prevented from or significantly delayed in achieving profitability.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the biopharmaceutical industry. For instance, the Drug Quality and Security Act imposes obligations on manufacturers of biopharmaceutical products related to product tracking and tracing. Among the requirements of this legislation, manufacturers are required to provide certain information regarding the product to individuals and entities to which product ownership is transferred, will be required to label products with a product identifier, and are required to keep certain records regarding the product. The transfer of information to subsequent product owners by manufacturers is also required to be done electronically. Manufacturers are also being required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, manufactures have product investigation, quarantine, disposition, and FDA, other comparable foreign regulatory authorities, and trading partner notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products that would result in serious adverse health consequences of death to humans, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

Compliance with the federal track and trace requirements may increase our operational expenses and impose significant administrative burdens. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

Our employees, independent contractors, consultants, commercial partners, principal investigators, CMOs, or CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, independent contractors, consultants, commercial partners, principal investigators, CMOs, or CROs could include intentional, reckless, negligent, or unintentional failures to comply with FDA regulations, comply with applicable fraud and abuse laws, provide accurate information to the FDA, properly calculate pricing information required by federal programs, report financial information or data accurately or disclose unauthorized activities to us. This misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter this type of misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Moreover, it is possible for a whistleblower to pursue a False Claims Act case against us even if the government considers the claim unmeritorious and declines to intervene, which could require us to incur costs defending against such a claim. If any such actions are instituted against us,

and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations, stock price and prospects, including the imposition of significant fines or other sanctions.

Violations of or liabilities under environmental, health and safety laws and regulations could subject us to fines, penalties or other costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures, the handling, use, storage, treatment and disposal of hazardous materials and wastes and the cleanup of contaminated sites. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We would incur substantial costs as a result of violations of or liabilities under environmental requirements in connection with our operations or property, including fines, penalties and other sanctions, investigation and cleanup costs and third-party claims. Although we generally contract with third parties for the disposal of hazardous materials and wastes from our operations, we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

Our internal computer systems, or those of our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our development programs.

Our internal computer systems, and those of our CROs, CMOs, information technology suppliers and other contractors and consultants are vulnerable to damage from computer viruses, cyber attacks and other unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of any of our product candidates could be delayed.

Risks related to our operations

We will need to expand the size of our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of March 31, 2019, we had 67 full-time employees, including 58 employees engaged in research and development. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;

- managing our internal development efforts effectively, including the clinical, FDA and comparable foreign regulatory review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and

- strengthening our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize RP1 and our other product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. The services include substantially all aspects of clinical trial management and manufacturing, as well as support for our financial reporting and accounting functions. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, we may not comply with our financial reporting and accounting obligations on a timely basis and we may not be able to obtain marketing approval of RP1 and our other product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring qualified new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize RP1 and our other product candidates and, accordingly, may not achieve our research, development and commercialization goals.

We are highly dependent on our key personnel, including Robert Coffin, Ph.D., our President and Chief Executive Officer; Philip Astley-Sparke, our Executive Chairman; Howard Kaufman, M.D., our Chief Medical Officer; and Colin Love, Ph.D., our Chief Operating Officer. If we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management and particularly on the services of our founders, as well as our other scientific, manufacturing, quality and medical personnel. Robert Coffin, Ph.D., our President and Chief Executive Officer, Philip Astley-Sparke, our Executive Chairman, and Colin Love, Ph.D., our Chief Operating Officer, were the founder and senior management team of BioVex Group, Inc., or BioVex, where they invented and developed T-Vec, the only oncolytic immunotherapy to receive FDA approval. BioVex was acquired by Amgen Inc., or Amgen, in 2011. Our Chief Medical Officer, Howard Kaufman, M.D., was the principal investigator for the pivotal study upon which T-Vec was approved and previously served as President of the Society for the Immunotherapy of Cancer. We believe that their drug discovery and development experience, and overall biopharmaceutical company management experience, would be difficult to replace. The loss of the services of our key personnel and any of our other executive officers, key employees, and scientific and medical advisors, and our inability to find suitable replacements, could result in delays in product development and harm our business. Furthermore, the historical results, past performance and/or acquisitions of companies with which our founders were affiliated, including BioVex, do not necessarily predict or guarantee similar results for our company.

We conduct our operations at our facilities near Boston, Massachusetts and near Oxford, England, each of which are in regions that are home to many other biopharmaceutical companies and many academic and research institutions.

Competition for skilled personnel is intense and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We expect that we will need to recruit talent from outside of these regions, and doing so may be costly and difficult.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock option grants that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, these employment agreements generally provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key man" insurance policies on the lives of any of these individuals or the lives of any of our other employees.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.

In connection with the audits of our consolidated financial statements as of and for the years ended March 31, 2019, 2018 and 2017, we identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, our stock price and ability to access the capital markets in the future.

The material weaknesses we identified were as follows:

- We did not design or maintain an effective control environment commensurate with our financial reporting requirements. We lacked a sufficient number of professionals with an appropriate level of accounting knowledge, training and experience to appropriately analyze, record and disclose accounting matters timely and accurately. Additionally, the limited personnel resulted in our inability to consistently establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives, as demonstrated by, among other things, our insufficient segregation of duties in our accounting function. This material weakness further contributed to the material weakness below.

- We did not design and maintain formal accounting policies, processes and controls to analyze, account for and disclose complex transactions, including accounting for preferred stock, stock-based compensation, warrant liabilities and leases.

Each of these control deficiencies could result in a misstatement of our accounts or disclosures that would result in a material misstatement of our annual or interim consolidated financial statements that would not be prevented or detected, and accordingly, we determined that these control deficiencies constitute material weaknesses.

These material weaknesses also resulted in adjustments to preferred stock, stock compensation expense, warrant liability and deferred rent in our consolidated financial statements as of and for the year ended March 31, 2017, which were recorded prior to their issuance.

Prior to the completion of our IPO, we were a private company with limited accounting personnel to adequately execute our accounting processes and other supervisory resources with which to address our internal control over financial reporting. We have implemented, and continue to implement, measures designed to improve our internal control over financial reporting and remediate the control deficiencies that led to these material weaknesses. To date, we have hired additional finance and accounting personnel and have engaged a third-party consulting firm to assist us in the design and documentation of appropriate controls. We are continuing these efforts in order to design and implement our financial control environment, including the establishment of controls to account for and disclose complex transactions.

We cannot assure you that the measures we have taken to date, and actions we intend to take in the future, will be sufficient to remediate the control deficiencies that led to these material weaknesses in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses. In addition, neither our management nor an independent registered public accounting firm has performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act because no such evaluation has been required. Had we or our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional material weaknesses may have been identified. If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, or identify any additional material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, potentially resulting in restatements of our financial statements, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports and applicable Nasdaq listing requirements, investors may lose confidence in our financial reporting, and our share price may decline as a result.

If we fail to establish and maintain proper and effective internal controls over financial reporting our ability to produce accurate and timely financial statements could be impaired.

We are required to maintain internal controls over financial reporting. Commencing with our fiscal year ending March 31, 2020, we must perform system and process design evaluation and testing of the effectiveness of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. Prior to our IPO, we were not required to test our internal controls within a specified period and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, if our independent registered public accounting firm determines that we continue to have a material weakness or significant deficiency in our internal control over financial reporting, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC, Nasdaq or other regulatory authorities.

We believe that any internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our consolidated financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Our disclosure controls and procedures were not effective as of March 31, 2019, and in any event may not prevent or detect all errors or acts of fraud.

We must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Based on the evaluation of our disclosure controls and procedures as of March 31, 2019, we concluded that, as of March 31, 2019, our disclosure controls and procedures were not effective at the reasonable assurance level as a result of the material weaknesses discussed above. Notwithstanding these material weaknesses, our management has concluded that the financial statements included elsewhere in this Annual Report present fairly, in all material respects, our financial position, results of operations and cash flows in conformity with generally accepted accounting principles. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;

- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party, their regulatory compliance status, and their existing products or product candidates and marketing approvals; and

- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense or intangible asset impairment charges. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business. Any of the foregoing may materially harm our business, financial condition, results of operations, stock price and prospects.

Unfavorable market and economic conditions may have serious adverse consequences on our business, financial condition, results of operations, stock price and prospects.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the economic climate and financial market conditions could adversely impact our business.

At March 31, 2019, we had $134.8 million of cash and cash equivalents and short-term investments. Although we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or short-term investments since that date, we cannot assure you that deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or short-term investments, or our ability to meet our financing objectives. Furthermore, our stock price may decline due, in part, to the volatility of the stock market and general economic downturns.

Exchange rate fluctuations may materially affect our results of operations and financial conditions.

Owing to the international scope of our operations, fluctuations in exchange rates, particularly between the U.S. dollar and the British pound and the euro, may adversely affect us. Although we are based in the United States, we have significant research and development operations in the United Kingdom, and source third-party manufacturing, consulting and other services in the United Kingdom and the European Union. As a result, our business and the price of our common stock may be affected by fluctuations in foreign exchange rates, which may have a significant impact on our results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place.

Risks related to our common stock

An active trading market for our common stock may not be sustained.

Our common stock began trading on the Nasdaq Global Select Market on July 19, 2018. Given the limited trading history of our common stock, there is a risk that an active trading market for shares of our common stock may not be sustained. In the absence of an active trading market for shares of our

common stock, our stockholders may not be able to sell their common stock at or above the price at which such stockholder acquired our common stock or at the time that they would like to sell.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

Our stock price has been and is likely to be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the price at which it was acquired. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- results of clinical trials of RP1 and our other product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to the development of RP1 and our other product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or drugs;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk factors" section.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under current and any potential future license and collaboration agreements and sales of our products, if approved. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we

use as a basis for valuing these awards change over time, including, our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- timing and cost of, and level of investment in, research and development activities relating to our current and any future product candidates, which will change from time to time;
- the total expenses we incur in connection with establishing, equipping, and operating our planned manufacturing facility and the actual timing of the facility becoming operational;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- the cost of manufacturing our current and any future product candidates, which may vary depending on the FDA's and comparable foreign regulatory authorities' guidelines and requirements, the quantity of production and the terms of any agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;
- the timing and outcomes of clinical and preclinical studies for RP1 and our other product candidates or competing product candidates;
- competition from existing and potential future products that compete with RP1 and our other product candidates, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of RP1 or our other product candidates;
- the level of demand for RP1 and our other product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future products that compete with RP1 and our other product candidates;
- our ability to commercialize RP1 and our other product candidates, if approved, inside and outside of the United States, either independently or working with third parties;
- the success of and our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

These factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our

common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue and/or earnings guidance we may provide.

We have broad discretion in how we use our cash, cash equivalents and investments, and may not use these resources effectively, which could affect our results of operations and cause our stock price to decline.

Our management has considerable discretion in the application of our cash, cash equivalents and investments. We intend to use our resources to fund our preclinical and clinical development programs and the establishment and equipping of our planned manufacturing facility, as well as for general corporate purposes, including working capital requirements and other operating expenses. As a result, investors will be relying upon management's judgment with only limited information about our specific intentions for the use of our resources. We may use our resources for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest our cash, cash equivalents and investments in a manner that does not produce income or that loses value.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock, which may never occur, as the only way to realize any return on their investment.

Our executive officers, directors, and stockholders and their affiliates who beneficially own more than 5% of our common stock exercise significant influence over our company, which limits your ability to influence corporate matters and could delay or prevent a change in corporate control.

Based on the number of shares outstanding as of March 31, 2019, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned a significant percentage of our voting stock. While these stockholders collectively own less than a majority of our voting stock, these stockholders will nevertheless continue to have significant influence over matters requiring stockholder approval. For example, these stockholders will continue to significantly influence elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

Conflicts of interest may arise because some members of our board of directors are representatives of our principal stockholders.

Certain of our principal stockholders or their affiliates are venture capital funds or other investment vehicles that could invest in entities that directly or indirectly compete with us. As a result of these relationships, when conflicts arise between the interests of the principal stockholders or their affiliates and the interests of other stockholders, members of our board of directors that are representatives of the principal stockholders may not be disinterested. Neither the principal stockholders nor the representatives of the principal stockholders on our board of directors, by the terms of our amended and restated certificate of incorporation, are required to offer us any transaction opportunity of which they become aware and could take any such opportunity for themselves or offer it to their other affiliates, unless such opportunity is expressly offered to them solely in their capacity as members of our board of directors.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the expiration of contractual or legal restrictions on resale lapse, the market price of our common stock could decline. These sales may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate, or to use equity as consideration for future acquisition.

In addition, approximately 6.9 million shares of common stock that are either subject to outstanding options, reserved for future issuance under our equity incentive plans or subject to outstanding warrants are eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

Certain holders of shares of our common stock, or their permitted transferees, are entitled to rights with respect to the registration under the Securities Act of approximately 19.2 million shares of our common stock pursuant to the amended and restated investors' rights agreement by and among us and certain of our stockholders. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the market price of our common stock.

We incur significantly increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, and related SEC and Nasdaq rules impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of our IPO. We intend to take advantage of this new legislation, but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

The rules and regulations applicable to public companies have substantially increased our legal and financial compliance costs and have made some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business. For example, these rules and regulations have made it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. The impact of

these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies, in part, on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which, in turn, could cause our stock price to decline.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and amended and restated bylaws may delay or prevent an acquisition of our company or a change in our management. These provisions include a classified board of directors and the ability of our board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with our company. Although we believe these provisions collectively provide for an opportunity to obtain greater value for stockholders by requiring potential acquirers to negotiate with our board of directors, they would apply even if an offer rejected by our board of directors were considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for our stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and critical audit matters reporting, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we completed our IPO, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) March 31, 2024, (2) the last day of the fiscal year (a) in which we have total annual gross revenue of at least $1.07 billion or (b) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700.0 million as of the prior September 30th, and (3) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" which would allow us to take advantage of many of the same exemptions from disclosure requirements including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock

less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the Jumpstart Our Business Startups Act of 2012, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This exclusive-forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for corporate disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. If a court were to find this exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

Our certificate of incorporation currently further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. Following a November 2018 decision of the Delaware Court of Chancery, we understand that this provision is invalid. We do not intend to enforce this provision, and we intend to seek the approval of our shareholders at the 2019 annual meeting to amend our certificate of incorporate to remove this provision.

Item 1B. Unresolved staff comments

None.

Item 2. Properties

Our current corporate headquarters are located in Woburn, Massachusetts. We lease this facility, which consists of approximately 4,000 square feet. Our Woburn lease expires in March 2021. In June 2019, we entered into a lease for another facility located in Woburn, Massachusetts, which consists of approximately 18,712 square feet. The term of the lease is approximately ten years, with an option for us to extend the lease by an additional five years. We intend to use this facility as our corporate headquarters upon the completion of planned renovations, which we expect will occur in the fourth

calendar quarter of 2019. We also lease an approximately 12,000 square-foot facility in Oxfordshire, United Kingdom, containing research and development, laboratory and office space. This lease expires in April 2026 and we have the right to terminate it in April 2021.

In June 2018, we signed a lease for an approximately 63,000 square-foot facility in Framingham, Massachusetts to house our manufacturing operations and our translational science laboratory. Our plan is to have the facility ready to produce clinical-grade material during the first half of 2020 and ultimately to be able to support commercial product launch. Pursuant to the lease agreement, the lease term commenced in November 2018. The rent commencement date is estimated to be August 2019. The initial lease term is ten years from the rent commencement date and includes two optional five-year extensions.

We believe that our existing and planned facilities will be adequate to meet our planned needs and that our leases can be renewed, or suitable alternative spaces will be available in the future, on commercially reasonable terms.

Item 3. Legal proceedings

We are not currently a party to any material legal proceedings.

Item 4. Mine safety disclosures

Not applicable.

PART II

Item 5. Market for registrant's common equity, related stockholder matters and issuer purchases of equity securities

Our common stock has been listed on the Nasdaq Global Market under the symbol "REPL" since July 19, 2018. Prior to that date, there was no public trading market for our common stock.

Holders of common stock

As of June 21, 2019, there were approximately 11 holders of record of our common stock. This number does not reflect beneficial owners whose shares are held in street name.

Dividend policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, contractual restrictions, business prospects, general business conditions and other factors that our board of directors may deem relevant.

Recent sales of unregistered securities

None.

Use of proceeds from registered securities

On July 24, 2018, we closed our initial public offering, or IPO, in which we sold an aggregate of 6,700,000 shares of common stock at a price to the public of $15.00 per share. On July 30, 2018 we sold an additional 707,936 shares of common stock at a price to the public of $15.00 per share in connection with the partial exercise of the underwriters' option to purchase 1,005,000 additional shares of common stock. The aggregate offering price for shares sold in the offering was $111.1 million. After deducting underwriting discounts, commissions and offering expenses paid or payable by us of approximately $7.8 million, the net proceeds from the offering were approximately $103.3 million. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates. The offer and sale of all of the shares in the IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333- 225846), which was declared effective by the SEC on July 19, 2018 . No additional shares were registered. There has been no material change in the planned use of proceeds from our IPO as described in our Registration Statement. We invested the funds received in short-term, interest-bearing investment-grade securities and government securities, including commercial papers, U.S. Government Agencies bonds, U.S. Treasury bills and bonds and corporate debt securities.

Issuer purchases of equity securities

Not applicable.

Item 6. Selected financial data

You should read the following selected consolidated financial data together with our consolidated financial statements and the related notes appearing at the end of this Annual Report on Form 10-K and the "Management's discussion and analysis of financial condition and results of operations" section

of this Annual Report on Form 10-K. We have derived the consolidated statement of operations data for the years ended March 31, 2019, 2018 and 2017 and the consolidated balance sheet data as of March 31, 2019 and 2018 from our audited consolidated financial statements appearing at the end of this Annual Report on Form 10-K. Our historical results are not necessarily indicative of results that should be expected in any future period.

	Year Ended March 31,		
	2019	2018	2017
Consolidated Statement of Operations Data:			
Operating expenses:			
Research and development	$ 22,173	$ 13,516	$ 6,936
General and administrative	8,773	5,713	2,711
Total operating expenses	30,946	19,229	9,647
Loss from operations	(30,946)	(19,229)	(9,647)
Other income:			
Research and development incentives	2,528	2,267	1,442
Investment income	2,585	288	25
Change in fair value of warrant liability	(5,452)	(972)	(150)
Other income (expense), net	451	(2,056)	626
Total other income (expense), net	112	(473)	1,943
Net loss	(30,834)	(19,702)	(7,704)
Net loss attributable to common stockholders	$ (30,834)	$ (19,702)	$ (7,704)
Net loss per share attributable to common stockholders—basic and diluted(1)	$ (1.33)	$ (3.96)	$ (1.55)
Weighted average common shares outstanding—basic and diluted(1)	23,198,400	4,978,539	4,973,439

(1) See Note 11 to our consolidated financial statements appearing at the end of this filing for further details on the calculation of basic and diluted net loss per share attributable to common stockholders.

	March 31,	
	2019	2018
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 134,811	$ 65,028
Working capital(1)	131,096	59,539
Total assets	154,326	65,151
Convertible preferred stock	—	86,361
Total stockholders' equity (deficit)	137,856	(28,068)

(1) We define working capital as current assets less current liabilities.

Item 7. Management's discussion and analysis of financial condition and results of operations

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report. In addition to historical information, this discussion and analysis contains forward-looking

statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this report, including those set forth under Item 1A. "Risk Factors" and under "Cautionary Note Regarding Forward-Looking Statements" in this Annual Report.

Overview

We are a clinical-stage biotechnology company committed to applying our leading expertise in the field of oncolytic immunotherapy to transform the lives of cancer patients. We use our proprietary Immulytic platform to design and develop product candidates that are intended to maximally activate the immune system against cancer.

Oncolytic immunotherapy is an emerging class of cancer treatment that exploits the ability of certain viruses to selectively replicate in and directly kill tumors, as well as induce a potent, patient-specific, anti-tumor immune response. Such oncolytic, or "cancer killing," viruses have the potential to generate an immune response targeted to an individual patient's particular set of tumor antigens, including neo-antigens that are uniquely present in tumors. Our product candidates incorporate multiple mechanisms of action into a practical "off-the-shelf" approach that is intended to maximize the immune response against a patient's cancer and to offer significant advantages over personalized vaccine approaches. We believe that the bundling of multiple approaches for the treatment of cancer into single therapies will simplify the development path of our product candidates, while also improving patient outcomes at a lower cost to the healthcare system than the use of multiple different drugs.

The foundation of our Immulytic platform consists of a proprietary, engineered strain of HSV-1 that has been "armed" with a fusogenic protein intended to substantially increase anti-tumor activity. Our platform enables us to incorporate various genes whose expression is intended to augment the inherent properties of HSV-1 to both directly destroy tumor cells and induce an anti-tumor immune response. We believe RP1 will be effective at killing tumors and inducing immunogenic, or immune-stimulating, tumor cell death and that it will be highly synergistic with immune checkpoint blockade therapies.

We are currently conducting a Phase 1/2 clinical trial with RP1 in approximately 150 patients. We have completed enrollment of the Phase 1 dose rising part of this clinical trial in which we are assessing the safety and tolerability of RP1 administered alone in 22 patients with mixed advanced solid tumor types, and following the review of the data by the SRC, have determined the dose regimen to be administered in the Phase 2 part of this clinical trial. We are completing enrollment of a Phase 1 expansion cohort of approximately 12 patients in which we are assessing the safety and tolerability of RP1 administered in combination with an anti-PD1 therapy at the determined Phase 2 dose level. One patient with MSI-H/dMMR remains to be enrolled in the expansion cohort.

The Phase 2 part of this clinical trial is designed to assess the safety and efficacy of RP1 in combination with an anti-PD1 therapy in four cohorts of approximately 30 patients with melanoma, non-melanoma skin cancers, bladder cancer and MSI-H/dMMR. Following SRC review of the Phase 1 data to date, including data from the expansion cohort receiving RP1 with anti-PD1 therapy, we have opened enrollment in the United States and the United Kingdom of the melanoma, bladder cancer, and non-melanoma skin cancer Phase 2 cohorts, and will open enrollment of the MSI-H-dMMR Phase 2 cohort after a final evaluable MSI-H/dMMR patient has been enrolled in the Phase 1 expansion cohort without safety concerns. In the Phase 2 part of the clinical trial we are also evaluating efficacy under the clinical trial protocol, primarily on the basis of the proportion of patients who have a response within each tumor type cohort. Responses are either defined as a partial response (a 30% or greater reduction in tumor size) or a complete response (a complete eradication of the disease). We

then intend to analyze each cohort's data to determine the indications that merit progressing into further clinical development.

We have entered into a collaboration agreement with BMS, under which it has granted us a non-exclusive, royalty-free license to, and is supplying at no cost, its anti-PD-1 therapy, nivolumab, for use in combination with RP1 in this clinical trial. BMS has no further development-related obligations under this collaboration.

We have also entered into a collaboration agreement with Regeneron under which we intend to conduct clinical development of our product candidates in combination with cemiplimab. For each clinical trial conducted under this collaboration, Regeneron will fund one-half of the clinical trial costs, supply cemiplimab at no cost, and grant us a non-exclusive, royalty-free license to cemiplimab for use in the clinical trial. The first planned clinical trial under this collaboration is a randomized, controlled Phase 2 clinical trial of RP1 in combination with cemiplimab, versus cemiplimab alone, in approximately 240 patients with CSCC. Initial study site activation is currently underway in the United States and Australia, with study initiation expected in August 2019. If compelling clinical data are generated demonstrating the benefits of the combined treatment, we believe the data from this Phase 2 clinical trial could support a filing with regulatory authorities for marketing approval.

We are also developing additional product candidates, RP2 and RP3, built on our Immulytic platform, that are further engineered to enhance anti-tumor immune responses and intended to address additional tumor types. RP2 has been engineered to express an antibody-like molecule that blocks the activity of CTLA-4, a protein that inhibits the immune response to tumors. RP3 is engineered with the intent of not only blocking the activity of CTLA-4, but also to further stimulate an anti-tumor response through activation of the immune co-stimulatory pathways through expression of the ligands for CD40 and 4-1BB.

We began operations as Replimune Limited, an English limited company that was incorporated in 2015. On July 5, 2017, Replimune Group, Inc., a Delaware corporation, was incorporated and, on July 10, 2017, the shareholders of Replimune Limited effected a share-for-share exchange pursuant to which they exchanged their outstanding shares in Replimune Limited for shares in Replimune Group, Inc., on a one-for-one basis.

In addition, the holders of warrants to purchase shares of series seed preferred stock and stock options to acquire Replimune Limited capital stock canceled their warrants and stock options in Replimune Limited and were issued replacement warrants and stock options to acquire Replimune Group, Inc. capital stock on a one-for-one basis. We refer to these transactions collectively as the reorganization. Upon completion of the reorganization, the historical consolidated financial statements of Replimune Limited became the historical consolidated financial statements of Replimune Group, Inc. because the reorganization was accounted for similar to a reorganization of entities under common control due to the high degree of common ownership of Replimune Limited and Replimune Group, Inc. and lack of economic substance to the transaction. We concluded that the reorganization resulted in no change in the material rights and preferences of each respective class of equity interests and no change in the fair value of each respective class of equity interests before and after the reorganization. On December 8, 2017, Replimune Limited transferred all outstanding shares of its wholly owned subsidiary, Replimune, Inc., to Replimune Group, Inc., a Delaware corporation. Replimune Group, Inc. is the sole shareholder of Replimune Limited, Replimune, Inc. and Replimune Securities Corporation, a Massachusetts corporation that was incorporated in November 2017.

Financial overview

Since our inception, we have devoted substantially all of our resources to developing our Immulytic platform and our lead product candidate, RP1, building our intellectual property portfolio, conducting research and development of our product candidates, business planning, raising capital and providing

general and administrative support for our operations. To date, we have financed our operations primarily with proceeds from the sale of equity securities. We do not have any products approved for sale and have not generated any revenue from product sales. On July 24, 2018, we completed our initial public offering ("IPO") of our common stock and issued and sold 6,700,000 shares of our common stock at a public offering price of $15.00 per share, resulting in net proceeds of approximately $93.5 million after deducting underwriting discounts and commissions but before deducting offering costs. On July 30, 2018, we issued and sold an additional 707,936 shares of our common stock at the IPO price of $15.00 per share pursuant to the underwriters' partial exercise of their option to purchase additional shares of common stock, resulting in additional net proceeds of approximately $9.9 million after deducting discounts and commissions and other offering expenses.

Since our inception, we have incurred significant operating losses. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more of our product candidates. Our net losses were $30.8 million, $19.7 million and $7.7 million for the years ended March 31, 2019, 2018 and 2017, respectively. As of March 31, 2019, we had an accumulated deficit of $59.8 million. These losses have resulted primarily from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years.

We anticipate that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. In addition, we expect to continue to incur additional costs associated with operating as a public company. We expect that our expenses and capital requirements will increase substantially if and as we:

- conduct our current and future clinical trials with RP1;
- progress the preclinical and clinical development of RP2 and RP3;
- establish, equip, and operate our own in-house manufacturing facility;
- seek to identify and develop additional product candidates;
- seek marketing approvals for any of our product candidates that successfully complete clinical trials, if any;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire and retain additional clinical, quality control, scientific and finance personnel;
- acquire or in-license other drugs and technologies; and
- add operational, financial and management information systems and personnel, including personnel to support our research and development programs, any future commercialization efforts and our continued transition to operating as a public company.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for RP1 or our other product candidates. If we obtain regulatory approval for any of our product candidates and do not enter into a commercialization partnership in any jurisdiction (which we currently do not intend to do in the United States), we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing, and distribution.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution, or licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back, or discontinue the development and commercialization of one or more of our product candidates.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of March 31, 2019, we had cash and cash equivalents and short-term investments of $134.8 million. We believe that our existing cash and cash equivalents and short-term investments will enable us to fund our operating expenses and capital expenditure requirements through at least 12 months from the issuance of the consolidated financial statements included in this Annual Report on Form 10-K.

See "—Liquidity and capital resources" and "Risk factors—Risks related to our financial position and need for additional capital."

Components of our results of operations

Revenue

To date, we have not generated any revenue from product sales as we do not have any approved products and do not expect to generate any revenue from the sale of products in the near future. If our development efforts for RP1 or any other product candidates that we may develop in the future are successful and result in regulatory approval, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from those collaborations or license agreements.

Operating expenses

Our expenses since inception have consisted solely of research and development costs and general and administrative costs.

Research and development expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts and the development of RP1 and our other product candidates, and include:

- expenses incurred under agreements with third parties, including clinical research organizations, or CROs, that conduct research, preclinical activities and clinical trials on our behalf as well as contract manufacturing organizations, or CMOs, that manufacture our product candidates for use in our preclinical and clinical trials;

- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;

- costs of outside consultants, including their fees, stock-based compensation and related travel expenses;
- the costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- costs related to compliance with regulatory requirements in connection with the development of RP1 and our other product candidates; and
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our consolidated financial statements as prepaid or accrued research and development expenses.

Our direct external research and development expenses are tracked on a program-by-program basis and consist of costs, such as fees paid to consultants, contractors, CMOs, and CROs in connection with our preclinical and clinical development activities. To date, we have not allocated expenses to our earlier-stage programs for RP2 and RP3. In addition, we do not allocate employee costs, costs associated with our discovery efforts, laboratory supplies, and facilities, including depreciation or other indirect costs, to specific product development programs because these costs are deployed across multiple product development programs and, as such, are not separately classified.

The table below summarizes our research and development expenses by product candidate or development program for each of the periods presented:

	Year Ended March 31,		
	2019	2018	2017
	(Amounts in thousands)		
RP1	$ 9,685	$ 7,250	$ 3,874
Unallocated research and development expenses	12,488	6,266	3,062
Total research and development expenses	$ 22,173	$ 13,516	$ 6,936

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will continue to increase for the foreseeable future as we initiate additional clinical trials of RP1, complete preclinical development and pursue initial stages of clinical development of RP2 and RP3 and continue to discover and develop additional product candidates. The successful development and commercialization of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the following:

- the scope, rate of progress, expense and results of our ongoing clinical trials of RP1, as well as of any future clinical trials of RP2 and RP3 or other product candidates and other research and development activities that we may conduct;
- the number and scope of preclinical and clinical programs we decide to pursue;
- our ability to maintain our current research and development programs and to establish new ones;
- uncertainties in clinical trial design and patient enrollment rates;

- the successful completion of clinical trials with safety, tolerability, and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- the receipt of regulatory approvals from applicable regulatory authorities;
- our success in establishing, equipping, and operating a manufacturing facility, or securing manufacturing supply through relationships with third parties;
- our ability to obtain and maintain patents, trade secret protection, and regulatory exclusivity, both in the United States and internationally;
- our ability to protect our rights in our intellectual property portfolio;
- the commercialization of our product candidates, if and when approved;
- the acceptance of our product candidates, if approved, by patients, the medical community, and third-party payors;
- our ability to successfully develop our product candidates for use in combination with third-party products or product candidates;
- negative developments in the field of immuno-oncology;
- competition with other products; and
- significant and changing government regulation and regulatory guidance.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant trial delays due to patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development. We may never succeed in obtaining regulatory approval for any of our product candidates.

General and administrative expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, corporate and business development and administrative functions. General and administrative expenses also include professional fees for legal, patent, accounting, auditing, tax and consulting services; travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expect that our general and administrative expenses will increase in the future as we increase our general and administrative headcount to support our continued research and development and potential commercialization of our product candidates. We also expect to continue to incur increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements; director and officer insurance costs; and investor and public relations costs.

Other income (expense), net

Research and development incentives

Research and development incentives consists of reimbursements of research and development expenditures. We participate, through our subsidiary in the United Kingdom, in the research and

development program provided by the United Kingdom tax relief program, such that a percentage of up to 14.5% of our qualifying research and development expenditures are reimbursed by the United Kingdom government, and such incentives are reflected as other income.

Change in fair value of warrant liability

In connection with the issuance of the series seed preferred stock, we issued to the series seed preferred stockholders warrants to purchase shares of series seed preferred stock. Prior to the completion of our IPO, we classified the warrants as a liability on our consolidated balance sheets. We remeasured the warrant liability to fair value at each reporting date and recognized changes in the fair value of the warrant liability as a component of other income (expense), net in our consolidated statements of operations.

Effective upon the completion of our IPO, the warrants to purchase shares of series seed preferred stock became exercisable for shares of common stock instead of shares of preferred stock, and the warrant liability was reclassified to additional paid-in capital. As a result, effective upon the completion of our IPO, we no longer recognize changes in the fair value of the warrant liability as other income (expense), net in our consolidated statements of operations.

Investment income

Interest income consists of income earned on our cash and cash equivalents and short-term investments.

Other income (expense), net

Other income (expense), net consists primarily of realized and unrealized foreign currency transaction gains and losses.

Income taxes

Since our inception and through March 31, 2019, we have not recorded any income tax benefits for the net losses we incurred in each jurisdiction in which we operate, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss carryforwards will not be realized.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act, or the Tax Act. The Tax Act includes a number of changes to existing tax law, including, among other things, a permanent reduction in the federal corporate income tax rate from a top marginal rate of 35% to a flat rate of 21%, effective as of January 1, 2018, as well as limitation of the deduction for net operating losses to 80% of annual taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such net operating losses may be carried forward indefinitely). Under the Tax Act, our deferred tax assets and liabilities (before valuation allowance) were remeasured at the lower federal tax rate, resulting in an increase to our income tax provision with an equal and offsetting reduction in our valuation allowance. We completed our final determination of the remeasurement of our deferred tax assets and liabilities for the year ended March 31, 2019 under SEC Staff Accounting Bulletin No. 118 and we have not recorded any adjustments to the provisional amounts recorded at March 31, 2018.

Results of operations

Comparison of the years ended March 31, 2019 and 2018

The following table summarizes our results of operations for the years ended March 31, 2019 and 2018:

	Year Ended March 31, 2019	2018	Change
	(Amounts in thousands)		
Operating expenses:			
Research and development	$ 22,173	$ 13,516	$ 8,657
General and administrative	8,773	5,713	3,060
Total operating expenses	30,946	19,229	11,717
Loss from operations	(30,946)	(19,229)	(11,717)
Other income (expense):			
Research and development incentives	2,528	2,267	261
Investment income	2,585	288	2,297
Change in fair value of warrant liability	(5,452)	(972)	(4,480)
Other income (expense), net	451	(2,056)	2,507
Total other income (expense), net	112	(473)	585
Net loss	$ (30,834)	$ (19,702)	$ (11,132)

Research and development expenses

	Year Ended March 31, 2019	2018	Change
	(Amounts in thousands)		
Direct research and development expenses by program:			
RP1	$ 9,685	$ 7,250	$ 2,435
Unallocated research and development expenses:			
Personnel related (including stock-based compensation)	7,534	4,120	3,414
Other	4,954	2,146	2,808
Total research and development expenses	$ 22,173	$ 13,516	$ 8,657

Research and development expenses for the year ended March 31, 2019 were $22.2 million, compared to $13.5 million for the year ended March 31, 2018. The increase of $8.7 million was due primarily to an increase of approximately $2.4 million in direct research costs associated with RP1 and an approximately $6.2 million increase in our unallocated research and development costs. The increase in RP1 costs was due primarily to an increase in clinical trial costs in the year ended March 31, 2019 associated with our ongoing Phase 1/2 clinical trial, which commenced in the United Kingdom in October 2017.

The increase in unallocated research and development expenses reflected an increase of $3.4 million in personnel-related costs, including stock-based compensation, and an increase of $2.8 million in other costs. The increase in personnel-related costs largely reflected the hiring of additional personnel in our research and development functions as we began work on our planned Phase 2 clinical trial of RP1 in patients with CSCC. Personnel-related costs for the years ended March 31, 2019 and 2018 included stock-based compensation expense of $2.7 million and $0.8 million,

respectively. Other costs increased primarily due to purchases of supplies used across all of our product candidates.

General and administrative expenses

General and administrative expenses were $8.8 million for the year ended March 31, 2019, compared to $5.7 million for the year ended March 31, 2018. The increase of $3.1 million primarily reflected increases of $2.1 million in personnel related costs and increases of $1.3 million in facility and other variable costs partially offset by decreases of $0.3 million in professional fees. The increase in personnel related costs was due to the hiring of additional personnel in our general and administrative functions as we expanded our operations in the United States. The decrease in professional fees was due primarily to reduced legal fees after the completion of our IPO. The increase in facility and other variable costs was due primarily to an increase in costs associated with our directors and officers insurance.

Total other income (expense), net

Other income (expense) was $0.1 million for the year ended March 31, 2019, compared to $(0.5) million for the year ended March 31, 2018. The increase of $0.6 million was primarily attributable to a $0.3 million increase in research and development incentives, a $2.3 million increase in investment income due to the reinvestment of our IPO proceeds received in July 2018 and $2.5 million increase in other income due primarily to changes in foreign currency exchange rates of Great British Pounds to United States Dollars, partially offset by a $4.5 million charge related to the change in the fair value of the warrant liability.

Comparison of the years ended March 31, 2018 and 2017

The following table summarizes our results of operations for the years ended March 31, 2018 and 2017:

	Year Ended March 31,		
	2018	2017	Change
	(Amounts in thousands)		
Operating expenses:			
Research and development	$ 13,516	$ 6,936	$ 6,580
General and administrative	5,713	2,711	3,002
Total operating expenses	19,229	9,647	9,582
Loss from operations	(19,229)	(9,647)	(9,582)
Other income (expense):			
Research and development incentives	2,267	1,442	825
Investment income	288	25	263
Change in fair value of warrant liability	(972)	(150)	(822)
Other income (expense), net	(2,056)	626	(2,682)
Total other income (expense), net	(473)	1,943	(2,416)
Net loss	$ (19,702)	$ (7,704)	$ (11,998)

Research and development expenses

	Year Ended March 31,		
	2018	2017	Change
	(Amounts in thousands)		
Direct research and development expenses by program:			
RP1	$ 7,250	$ 3,874	$ 3,376
Unallocated research and development expenses:			
Personnel related (including stock-based compensation)	4,120	2,121	1,999
Other	2,146	941	1,205
Total research and development expenses	$ 13,516	$ 6,936	$ 6,580

Research and development expenses for the year ended March 31, 2018 were $13.5 million, compared to $6.9 million for the year ended March 31, 2017. The increase of $6.6 million was due primarily to an increase of approximately $3.4 million in direct research costs associated with RP1 and an approximately $3.2 million increase in our unallocated research and development costs. The increase in RP1 costs was due primarily to an increase in clinical trial costs in the year ended March 31, 2018 associated with our ongoing Phase 1/2 clinical trial, which commenced in the United Kingdom in October 2017.

The increase in unallocated research and development expenses reflected an increase of $2.0 million in personnel-related costs, including stock-based compensation, and an increase of $1.2 million in other costs. The increase in personnel-related costs was primarily due to the hiring of additional personnel in our research and development functions as we began work on our planned Phase 2 clinical trial of RP1 in patients with CSCC. Personnel-related costs for each of the years ended March 31, 2018 and 2017 included stock-based compensation expense of $0.8 million and $0.2 million, respectively. Other costs increased primarily due to purchases of supplies used across all of our product candidates.

General and administrative expenses

General and administrative expenses were $5.7 million for the year ended March 31, 2018, compared to $2.7 million for the year ended March 31, 2017. The increase of $3.0 million primarily reflected increases of $1.1 million in personnel related costs and $1.6 million in professional fees. The increase in personnel related costs was due to the hiring of additional personnel in our general and administrative functions as we expanded our operations in the United States. The increase in professional fees was due to costs associated with the preparation, audit and review of our financial statements and readiness to become a public company.

Total other income (expense), net

Other income (expense) was $(0.5) million for the year ended March 31, 2018, compared to $1.9 million for the year ended March 31, 2017. The decrease of $2.4 million was primarily attributable to a $2.7 million increase in the expense due to a change in foreign exchange rates and a $0.8 million increase in the expense due to a change in the fair value of the warrant liability, partially offset by a $0.8 million increase in expenditure reimbursements recognized under the research and development program provided by the United Kingdom government and a $0.3 million increase in investment income.

Liquidity and capital resources

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from our operations. We have not yet commercialized any of our product candidates, which are in various phases of preclinical and clinical development, and we do not expect to generate revenue from sales of any products for the foreseeable future, if at all.

Sources of liquidity

To date, we have financed our operations primarily with proceeds from the sale equity securities. Through March 31, 2019, we had received gross proceeds of approximately $198.0 million from our sales of common stock and preferred stock. As of March 31, 2019, we had cash and cash equivalents and short-term investments of $134.8 million.

On July 24, 2018, we completed our IPO and issued and sold 6,700,000 shares of our common stock at a public offering price of $15.00 per share, resulting in net proceeds of $93.5 million after deducting underwriting discounts and commissions but before deducting offering costs. On July 30, 2018, we issued and sold an additional 707,936 shares of our common stock at the IPO price of $15.00 per share pursuant to the underwriters' partial exercise of their option to purchase additional shares of our common stock, resulting in additional net proceeds of $9.9 million after deducting discounts and commissions and other offering expenses.

Cash flows

The following table summarizes our cash flows for each of the periods presented:

	Year Ended March 31,		
	2019	2018	2017
	(in thousands)		
Net cash used in operating activities	$ (25,378)	$ (16,014)	$ (7,077)
Net cash used in investing activities	(65,944)	(44,046)	(238)
Net cash provided by financing activities	101,390	54,752	15,000
Effect of exchange rate changes on cash and cash equivalents	(839)	2,297	(1,419)
Net increase in cash, cash equivalents and restricted cash	$ 9,229	$ (3,011)	$ 6,266

Operating activities

During the year ended March 31, 2019, net cash used in operating activities was $25.4 million, primarily resulting from our net loss of $30.8 million and net cash used by changes in our operating assets and liabilities of $1.3 million, partially offset by non-cash charges of $6.7 million. Net cash used by changes in our operating assets and liabilities for the year ended March 31, 2019 consisted primarily of a $0.1 million increase in accounts payable, partially offset by a $0.8 million decrease in prepaid expenses and other current assets, a $0.3 million increase in the research and development incentives receivable from the United Kingdom government due to the timing and amount of our qualifying expenditures and a $0.3 million increase in prepaid expenses and other current assets.

During the year ended March 31, 2018, net cash used in operating activities was $16.0 million, primarily resulting from our net loss of $19.7 million, partially offset by net cash provided by changes in our operating assets and liabilities of $1.9 million and non-cash charges of $1.8 million. Net cash provided by changes in our operating assets and liabilities for the year ended March 31, 2018 consisted primarily of a $1.6 million increase in accounts payable and a $1.4 million increase in accrued expenses and other current liabilities, partially offset by a $0.8 million increase in the research and development incentives receivable from the United Kingdom government due to the timing and amount of our qualifying expenditures and a $0.3 million increase in prepaid expenses and other current assets due to CRO deposits related to the ongoing Phase 1/2 clinical trial for RP1.

During the year ended March 31, 2017, net cash used in operating activities was $7.1 million, primarily resulting from our net loss of $7.7 million, partially offset by non-cash charges of $0.5 million, and net cash provided by changes in our operating assets and liabilities of $0.1 million. Net cash used by changes in our operating assets and liabilities for the year ended March 31, 2017 consisted primarily of a $0.2 million increase in accounts payable and a $1.4 million increase in accrued expenses due to accrued RP1 clinical trial costs, accrued compensation costs and accrued audit fees, partially offset by a $1.2 million increase in the research and development incentives receivable from the United Kingdom government due to the timing and amount of our qualifying expenditures and a $0.3 million increase in prepaid expenses and other current assets due to value-added tax receivables and CMO deposits for RP1 clinical trial supplies.

Investing activities

During the year ended March 31, 2019, net cash used in investing activities was $65.9 million, consisting of $189.9 million in purchases of available for sale securities and $2.6 million in purchases of property, plant and equipment, partially offset by $126.6 million in proceeds from maturities of short-term investments.

During the year ended March 31, 2018, net cash used in investing activities was $44.0 million, consisting of $52.5 million in purchases of available for sale securities and $0.1 million in purchases of property, plant and equipment, partially offset by $8.6 million in proceeds from maturities of short-term investments.

During the year ended March 31, 2017, net cash used in investing activities was $0.2 million, consisting of purchases of property, plant and equipment.

We expect that purchases of property, plant and equipment will increase over the next several years resulting from our intended establishment of our own in-house manufacturing facility.

Financing Activities

During the year ended March 31, 2019, net cash provided by financing activities was $101.4 million, consisting primarily of net cash proceeds of $103.3 million from our issuance of common stock in connection with our IPO and $0.2 million from the exercise of stock options, partially offset by $2.2 million of payments of issuance costs.

During the year ended March 31, 2018, net cash provided by financing activities was $54.8 million, primarily consisting of net proceeds from our issuance of series B convertible preferred stock, or series B preferred stock.

During the year ended March 31, 2017, net cash provided by financing activities was $15.0 million, primarily consisted of proceeds from our issuance of series A convertible preferred stock, or series A preferred stock.

Funding requirements

Our plan of operation is to continue implementing our business strategy, continue research and development of RP1 and our other product candidates and continue to expand our research pipeline and our internal research and development capabilities. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. In addition, we expect to continue to incur additional costs associated with operating as a public company. We expect that our expenses will increase substantially if and as we:

- conduct our current and future clinical trials of RP1;

- progress the preclinical and clinical development of RP2 and RP3;
- seek to identify and develop additional product candidates;
- seek marketing approvals for any of our product candidates that successfully complete clinical trials, if any;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- until our planned manufacturing facility is operational, require the manufacture by third parties of larger quantities of our product candidates for clinical development and potentially commercialization;
- maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other drugs and technologies; and
- add operational, financial and management information systems and personnel, including personnel to support our research and development programs, any future commercialization efforts and our continued transition to operating as a public company.

As of March 31, 2019, we had cash and cash equivalents and short-term investments of $134.8 million. We believe that our existing cash and cash equivalents and short-term investments will enable us to fund our operating expenses and capital expenditure requirements through at least 12 months from the issuance of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Because of the numerous risks and uncertainties associated with the development of RP1 and other product candidates and programs, and because the extent to which we may enter into collaborations with third parties for development of our product candidates is unknown, we are unable to estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our future capital requirements will depend on many factors, including those described in this section and above under "—Operating expenses—Research and development expenses."

In addition, we intend to establish, equip, and operate an in-house manufacturing facility to manufacture RP1 and our other product candidates. We expect that such a facility would require total capital expenditures of approximately $22.5 million to construct, net of approximately $8.9 million in tenant improvement costs.

Developing novel biopharmaceutical products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval for any product candidates or generate revenue from the sale of any products for which we may obtain marketing approval. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of therapies that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Adequate additional funds may not be available to us on acceptable terms, or at all. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of our equity or convertible debt securities, our shareholders' interest may be diluted, and the terms of these securities may include liquidation or other preferences and anti-dilution protections that could adversely affect the rights of our common stockholder. Additional debt or preferred equity financing, if available, may involve agreements that include restrictive covenants that may limit our ability to take specific actions, such as incurring debt adversely impact our ability to

conduct our business, and may require the issuance of warrants, which could potentially dilute our shareholders' interest.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technology, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or collaborations, strategic alliances or licensing arrangements with third parties when needed, we may be required to delay, limit, reduce and/or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual obligations and commitments

The following table summarizes our contractual obligations as of March 31, 2019 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments due by period				
	Total	Less than 1 year	1 to 3 years	4 to 5 years	More than 5 years
	(Amounts in thousands)				
Manufacturing commitments(1)	$ 4,694	$ 4,694	$ —	$ —	$ —
Operating lease commitments(2)	28,164	2,062	5,394	5,213	15,495
Total	$ 32,858	$ 6,756	$ 5,394	$ 5,213	$ 15,495

(1) Amounts in the table reflect commitments for costs associated with our external CMO, which we engaged to manufacture clinical trial materials.

(2) Amounts in the table reflect minimum payments due under (i) our two operating leases of laboratory and office space in Woburn, Massachusetts and Oxfordshire, United Kingdom, at a monthly commitment of $7 and $31, respectively, and (ii) our build-to-suit lease of approximately 63,000 square feet of office, manufacturing and laboratory space in Framingham, Massachusetts. Our lease in Woburn expires in March 2021, and our lease in Oxfordshire expires in April 2026 and is terminable by us in April 2021. The lease term for our Framingham lease commenced in November 2018, subject to the landlord completing certain agreed upon landlord improvements. The rent commencement date is estimated to be August 2019. The initial lease term is ten years from the rent commencement date and includes two optional five-year extensions.

We enter into contracts in the normal course of business with CROs, CMOs and other third parties for clinical trials and preclinical research studies and testing. Manufacturing and research commitments in the preceding table include agreements that are enforceable and legally binding on us and that specify all significant terms, including fixed or minimum quantities to be purchased; fixed, minimum or variable price provisions; and the approximate timing of the transaction. For obligations with cancellation provisions, the amounts included in the preceding table are limited to the non-cancelable portion of the agreement terms or the minimum cancellation fee.

Collaborations

BMS

On February 26, 2018, we entered into a Clinical Trial Collaboration and Supply Agreement with Bristol- Myers Squibb Company, or BMS. Pursuant to the agreement, BMS will provide to us, at no cost, nivolumab, its anti-PD-1 therapy, for use in combination with RP1 in our ongoing Phase 1/2 clinical trial. Under the agreement, we will sponsor, fund and conduct the clinical trial in accordance

with an agreed-upon protocol. Under the agreement, BMS granted us a non-exclusive, non-transferrable, royalty-free license (with a right to sublicense) under its intellectual property to use nivolumab in the clinical trial and has agreed to supply nivolumab, at its cost and for no charge to us, for use in the clinical trial. Both parties will own the study data produced in the clinical trial, other than study data related solely to nivolumab, which will belong solely to BMS or study data related solely to RP1, which will belong solely to us.

Unless earlier terminated, the agreement will remain in effect until (i) the completion of the clinical trial, (ii) all related clinical trial data have been delivered to both parties and (iii) the completion of any statistical analyses and bioanalyses contemplated by the clinical trial protocol or any analysis otherwise agreed upon by the parties. The agreement may be terminated by either party (i) in the event of an uncured material breach by the other party, (ii) in the event the other party is insolvent or in bankruptcy proceedings or (iii) for safety reasons. Upon termination, the licenses granted to us to use nivolumab in the clinical trial will terminate. The agreement contains representations, warranties, undertakings and indemnities customary for a transaction of this nature.

Regeneron

On May 29, 2018, we entered into a Master Clinical Trial Collaboration and Supply Agreement with Regeneron Pharmaceuticals, Inc., or Regeneron. Pursuant to the agreement we agreed to undertake one or more clinical trials with Regeneron for the administration of our product candidates in combination with cemiplimab, an anti-PD-1 therapy developed by Regeneron, across multiple solid tumor types, the first of which is intended to be our planned Phase 2 clinical trial of RP1 in patients with CSCC. Each clinical trial will be conducted pursuant to an agreed study plan which, among other things, will identify the name of the sponsor and which party will manage the particular study, and include the protocol, the budget and a schedule of clinical obligations. The first study plan related to the Phase 2 clinical trial in CSCC has been agreed.

Pursuant to the terms of the agreement, each party granted the other party a non-exclusive license of their respective intellectual property and agreed to contribute the necessary resources needed to fulfill their respective obligations, in each case, under the terms of agreed study plans. Development costs of a particular clinical trial will be split equally. The agreement contains representations, warranties, undertakings and indemnities customary for a transaction of this nature. The agreement also contains certain covenants that restrict us from entering into a third-party arrangement with respect to the use of our product candidates in combination with an anti-PD-1 therapy and that restrict Regeneron from entering into a third-party arrangement with respect to the use of cemiplimab in combination with an HSV-1 virus, in each case, for the treatment of a tumor type that is the subject of a clinical trial to which the covenants apply. Unless otherwise mutually agreed in a future study plan, these covenants are only applicable to our planned Phase 2 clinical trial in CSCC, and expire upon the one-year anniversary of the commencement of the applicable study plan.

The agreement may be terminated by either party if (i) there is no active study plan for which a final study report has not been completed, (ii) the parties have not entered into a study plan for an additional clinical trial within a period of time after the delivery of the most recent final study report or (iii) in the event of a material breach.

Critical accounting policies and significant judgments and estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets

and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in greater detail in Note 2 to our consolidated financial statements appearing elsewhere in the Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Accrued research and development expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:

- CROs in connection with performing research activities and conducting preclinical studies and clinical trials on our behalf;
- CMOs in connection with the production of preclinical and clinical trial materials;
- investigative sites or other service providers in connection with clinical trials;
- vendors in connection with preclinical and clinical development activities; and
- vendors related to product manufacturing and development and distribution of preclinical and clinical supplies.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CMOs and CROs that supply, conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Stock-based compensation

We measure stock-based awards granted to employees and directors based on their fair value on the date of the grant and recognize compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. We have to date only issued stock-based awards with service-based vesting conditions and record the expense for these awards using the straight-line method. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and our expected dividend yield. See Note 10 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K for more information. Forfeitures are accounted for as they occur. The fair value of each stock-based award is estimated on the date of grant based on the fair value of our common stock on that same date.

Prior to the adoption of ASC 2018-07, for stock-based awards granted to consultants and non-employees, we recognize compensation expense over the period during which services are rendered by such non-employees and consultants until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is remeasured using the then-current fair value of our common stock and updated assumption inputs in the Black-Scholes option pricing model.

After the adoption of ASC 2018-07, for stock-based awards granted to consultants and non-employees, we measure stock-based these awards based on their fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. We have to date only issued stock-based awards with service-based vesting conditions and record the expense for these awards using the straight-line method. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and our expected dividend yield.

We classify stock-based compensation expense in our consolidated statements of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Off-balance sheet arrangements

We did not have any off-balance sheet arrangements during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Recently issued accounting pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Emerging growth company status

As an "emerging growth company," the Jumpstart Our Business Startups Act of 2012 permits us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected to "opt out" of this provision and, as a result, we will comply with new or

revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

Item 7A. Quantitative and qualitative disclosures about market risks

Interest rate sensitivity

As of March 31, 2019, we had cash and cash equivalents and short-term investments of $134.8 million, which consisted of cash equivalents, commercial paper and commercial debt securities. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our investment portfolio.

As of March 31, 2019, we had no debt outstanding and are therefore not subject to interest rate risk related to debt.

Foreign currency exchange risk

Our headquarters are located in the United States, where the majority of our general and administrative expenses are incurred in U.S. dollars. The majority of our research and development costs are incurred by our subsidiary in Oxfordshire, United Kingdom, whose functional currency is the British pound. We are exposed to foreign exchange rate risk. During the years ended March 31, 2019, 2018 and 2017, we recognized foreign currency transaction gains (losses) of $0.5 million, $(2.1) million and $0.6 million, respectively. These gains (losses) are primarily related to unrealized and realized foreign currency gains and losses as a result of transactions entered into by our United Kingdom subsidiary in currencies other than the British pound, primarily the euro. These foreign currency transaction gains (losses) were recorded as a component of other income (expense), net in our consolidated statements of operations. We believe that a 10% change in the exchange rate between the British pound and the euro would not have a material impact on our financial position or results of operations.

As we continue to grow our business, our results of operations and cash flows will be subject to fluctuations due to changes in foreign currency exchange rates, which could adversely impact our results of operations. To date, we have not entered into any foreign currency hedging contracts to mitigate our exposure to foreign currency exchange risk.

Item 8. Financial statements and supplementary data

See the consolidated financial statements filed as part of this Annual Report on Form 10-K as listed under Item 15 below.

Item 9. Changes in and disagreements with accountants on accounting and financial disclosures

Not Applicable.

Item 9A. Controls and procedures

Evaluation of disclosure controls and procedures

Disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, are controls and other procedures designed to ensure that information required to be disclosed in reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified by the rules and forms promulgated by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and

communicated to management, including the chief executive officer and the chief accounting officer, as appropriate, to allow timely decisions regarding required disclosure.

In connection with the preparation of this Annual Report on Form 10-K, we completed an evaluation, as of March 31, 2019, under the supervision of and with the participation of our management, including our Chief Executive Officer and Chief Accounting Officer, as to the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act).

It should be noted that any system of controls, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system will be met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of future events. Based upon the evaluation, our Chief Executive Officer and Chief Accounting Officer have concluded that, as of March 31, 2019, our disclosure controls and procedures were not effective at a reasonable assurance level due to the material weakness described below.

In connection with the audits of our consolidated financial statements as of and for the years ended March 31, 2019, 2018 and 2017, we identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses that we identified were as follows:

- We did not design or maintain an effective control environment commensurate with our financial reporting requirements. We lacked a sufficient number of professionals with an appropriate level of accounting knowledge, training and experience to appropriately analyze, record and disclose accounting matters timely and accurately. Additionally, the limited personnel resulted in our inability to consistently establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives, as demonstrated by, among other things, our insufficient segregation of duties in our accounting function. This material weakness further contributed to the material weakness below.

- We did not design and maintain formal accounting policies, processes and controls to analyze, account for and disclose complex transactions, including accounting for preferred stock, stock-based compensation, warrant liabilities and leases.

Each of these control deficiencies could result in a misstatement of our accounts or disclosures that would result in a material misstatement of our annual or interim consolidated financial statements that would not be prevented or detected, and accordingly, we determined that these control deficiencies constitute material weaknesses.

Management's report on internal control over financial reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by rules of the SEC for newly public companies. See also "Risk Factors—We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business."

Changes in internal control over financial reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fourth quarter of 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other information

None.

PART III

Item 10. Directors, executive officers and corporate governance

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended March 31, 2019.

The text of our Code of Business Conduct and Ethics, which applies to our directors and employees (including our principal executive officer, principal financial officer, and principal accounting officer or controller, and persons performing similar functions), is posted in the "Corporate Governance" section of our website, www.replimune.com. A copy of the Code of Business Conduct and Ethics can be obtained free of charge on our website. We intend to disclose on our website any amendments to, or waivers from, our Code of Business Conduct and Ethics that are required to be disclosed pursuant to the rules of the Securities and Exchange Commission and Nasdaq.

Item 11. Executive compensation

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange commission not later than 120 days after the close of our fiscal year ended March 31, 2019.

Item 12. Security ownership of certain beneficial owners and management and related stockholder matters

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange commission not later than 120 days after the close of our fiscal year ended March 31, 2019.

Item 13. Certain relationships and related transactions, and director independence

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange commission not later than 120 days after the close of our fiscal year ended March 31, 2019.

Item 14. Principal accountant fees and services

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange commission not later than 120 days after the close of our fiscal year ended March 31, 2019.

PART IV

Item 15. Exhibits and financial statement schedules

(a) 1. Consolidated Financial Statements.

For a list of the consolidated financial statements included herein, see Index on page F-1 of this report.

2. Financial Statement Schedules.

All required information is included in the financial statements or notes thereto.

3. List of Exhibits.

The documents listed in the Exhibit Index immediately preceding the signature page of this Annual Report on Form 10-K are incorporated by reference or are filed or furnished with this Annual Report on Form 10-K, in each case as indicated therein.

Item 16. 10-K summary

None.

Exhibit index

Exhibit Number	Exhibit Description	Incorporated by Reference		
		Form	Date	Number
3.1	Third Amended and Restated Certificate of Incorporation of Replimune Group, Inc.	8-K	July 24, 2018	3.1
3.2	Amended and Restated By-laws of Replimune Group, Inc.	8-K	July 24, 2018	3.2
4.1	Form of Common Stock Certificate of the Registrant.	S-1/A	July 10, 2018	4.1
4.2	Amended and Restated Investors' Rights Agreement, dated July 10, 2017, by and among the Registrant and the investors set forth therein.	S-1	June 22, 2018	4.2
4.3*	Description of Capital Stock.			
10.1	Form of Indemnification Agreement by and between the Registrant and its directors and officers.	S-1/A	July 10, 2018	10.1
10.2†	2017 Equity Compensation Plan and Sub-Plan for U.K. Employees and forms of agreements thereunder.	S-1/A	June 26, 2018	10.2
10.3†	2018 Omnibus Incentive Compensation Plan and Sub-Plan for U.K. Employees and forms of agreements thereunder.	S-1/A	July 10, 2018	10.3
10.4†	Employee Stock Purchase Plan.	S-1/A	July 10, 2018	10.4
10.5†	Employment Agreement, effective as of October 1, 2015, by and between Robert Coffin and Replimune, Inc.	S-1	June 22, 2018	10.5
10.6†	Employment Agreement, effective as of October 1, 2015, by and between Philip Astley-Sparke and Replimune, Inc.	S-1	June 22, 2018	10.6
10.7†	Employment Agreement, effective as of November 1, 2015, by and between Pamela Esposito and Replimune, Inc.	S-1	June 22, 2018	10.7
10.8†	Employment Agreement, dated as of June 22, 2018, by and between Howard Kaufman and Replimune, Inc.	S-1/A	July 10, 2018	10.8
10.9†	Employment Agreement, dated as of September 16, 2015, by and between Colin Love and Replimune Limited.	S-1/A	July 10, 2018	10.9
10.10†*	Employment Agreement, dated as of May 8, 2019, by and between Stephen Gorgol and Replimune, Inc.			
10.11	Lease, dated as of April 1, 2016, by and between Cummings Properties, LLC and the Registrant.	S-1	June 22, 2018	10.8
10.12	Lease, dated as of April 4, 2016, by and between MEPC Milton Park No. 1 Limited and MEPC Milton Park No. 2 Limited, and Replimune Limited.	S-1	June 22, 2018	10.9
10.13‡	Clinical Trial Collaboration and Supply Agreement, dated as of February 26, 2018, by and between Bristol-Myers Squibb Company and the Registrant.	S-1/A	July 10, 2018	10.12

Exhibit Number	Exhibit Description	Incorporated by Reference		
		Form	Date	Number
10.14‡	Master Clinical Trial Collaboration and Supply Agreement, dated as of May 29, 2018, by and between Regeneron Pharmaceuticals, Inc. and the Registrant.	S-1/A	July 17, 2018	10.13
10.15	Indenture of Lease, dated as of June 22, 2018, by and between CRP/King 33 NY Ave. Owner, L.L.C. and the Registrant.	S-1	June 22, 2018	10.12
10.16	Lease, dated as of June 7, 2019, by and between ND/CR Unicorn LLC and the Registrant.	8-K	June 13, 2019	10.1
21.1	Subsidiaries of the Registrant.	S-1/A	June 26, 2018	21.1
23.1*	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.			
31.1*	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).			
31.2*	Certification of the Chief Accounting Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).			
32.1**	Certification of the Chief Executive Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).			
32.2**	Certification of the Chief Accounting Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).			
101.INS*	XBRL Instance Document.			
101.SCH*	XBRL Taxonomy Extension Schema Document.			
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.			
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.			
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.			
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.			

* Filed herewith.

** Furnished and not filed herewith.

† Indicates management contract or compensatory plan.

‡ Indicates confidential treatment has been requested with respect to specific portions of this exhibit. Omitted portions have been filed with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

Signatures

Pursuant to the requirements of Section 13 or 15(d) of the Securities Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

REPLIMUNE GROUP, INC.

Date: June 28, 2019

By: /s/ ROBERT COFFIN

Robert Coffin, Ph.D.
President, Chief Executive Officer and Director

Pursuant to the requirements of the Securities Act of 1934, this report has been signed by the following persons in the capacities and on the dates indicated.

Name	Title	Date
/s/ ROBERT COFFIN Robert Coffin, Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	June 28, 2019
/s/ PHILIP ASTLEY-SPARKE Philip Astley-Sparke	Executive Chairman, Treasurer, Secretary and Director	June 28, 2019
/s/ STEPHEN GORGOL Stephen Gorgol	Chief Accounting Officer (Principal Financial and Accounting Officer)	June 28, 2019
/s/ KAPIL DHINGRA Kapil Dhingra	Director	June 28, 2019
/s/ HYAM LEVITSKY Hyam Levitsky	Director	June 28, 2019
/s/ JASON RHODES Jason Rhodes	Director	June 28, 2019
/s/ JOSEPH SLATTERY Joseph Slattery	Director	June 28, 2019
/s/ OTELLO STAMPACCHIA Otello Stampacchia	Director	June 28, 2019

Name	Title	Date
/s/ SANDER SLOOTWEG Sander Slootweg	Director	June 28, 2019
/s/ DIETER WEINAND Dieter Weinand	Director	June 28, 2019

REPLIMUNE GROUP, INC.

Financial Statements

For the Years Ended March 31, 2019, 2018 and 2017

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
Replimune Group, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Replimune Group, Inc. and its subsidiaries (the "Company") as of March 31, 2019 and 2018, and the related consolidated statements of operations, of comprehensive loss, of convertible preferred stock and stockholders' equity (deficit) and of cash flows for each of the three years in the period ended March 31, 2019 including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of March 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended March 31, 2019 in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
June 28, 2019

We have served as the Company's auditor since 2018.

REPLIMUNE GROUP, INC.

CONSOLIDATED BALANCE SHEETS

(Amounts in thousands, except share and per share amounts)

	March 31, 2019	March 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 25,704	$ 17,583
Short-term investments	109,107	43,968
Research and development incentives receivable	2,474	2,389
Prepaid expenses and other current assets	3,696	763
Total current assets	140,981	64,703
Property and equipment, net	12,159	370
Restricted cash	1,186	78
Total assets	$ 154,326	$ 65,151
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 7,084	$ 1,993
Accrued expenses and other current liabilities	2,801	3,171
Total current liabilities	9,885	5,164
Deferred rent, net of current portion	24	52
Warrant liability	—	1,642
Financing obligation	6,561	—
Total liabilities	16,470	6,858
Commitments and contingencies (Note 13)		
Convertible preferred stock (Series Seed, A and B), $0.001 par value; 0 and 1,975,968 shares authorized as of March 31, 2019 and 2018, respectively; 0 and 1,925,968 shares issued and outstanding as of March 31, 2019 and 2018, respectively	—	86,361
Stockholders' Equity (Deficit)		
Common stock, $0.001 par value; 150,000,000 and 27,314,288 shares authorized (inclusive of 0 and 26,258 shares of common A stock) as of March 31, 2019 and 2018, respectively; 31,656,950 and 5,007,485 shares issued and outstanding (inclusive of 0 and 26,258 shares of common A stock) as of March 31, 2019 and 2018, respectively	32	5
Additional paid-in capital	198,645	1,097
Accumulated deficit	(59,766)	(28,932)
Accumulated other comprehensive loss	(1,055)	(238)
Total stockholders' equity (deficit)	137,856	(28,068)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 154,326	$ 65,151

The accompanying notes are an integral part of these consolidated financial statements.

REPLIMUNE GROUP, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(Amounts in thousands, except share and per share amounts)

	Year Ended March 31,		
	2019	2018	2017
Operating expenses:			
Research and development	$ 22,173	$ 13,516	$ 6,936
General and administrative	8,773	5,713	2,711
Total operating expenses	30,946	19,229	9,647
Loss from operations	(30,946)	(19,229)	(9,647)
Other income (expense):			
Research and development incentives	2,528	2,267	1,442
Investment income	2,585	288	25
Change in fair value of warrant liability	(5,452)	(972)	(150)
Other income (expense), net	451	(2,056)	626
Total other income (expense), net	112	(473)	1,943
Net loss	(30,834)	(19,702)	(7,704)
Net loss attributable to common shareholders	$ (30,834)	$ (19,702)	$ (7,704)
Net loss per share attributable to common shareholders, basic and diluted	$ (1.33)	$ (3.96)	$ (1.55)
Weighted average common shares outstanding—basic and diluted	23,198,400	4,978,539	4,973,439

The accompanying notes are an integral part of these consolidated financial statements.

REPLIMUNE GROUP, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Amounts in thousands)

	Year Ended March 31,		
	2019	2018	2017
Net loss	$ (30,834)	$ (19,702)	$ (7,704)
Other comprehensive income (loss):			
Foreign currency translation gain (loss)	(897)	2,376	(1,437)
Net unrealized gain (loss) on short-term investments, net of tax	80	(65)	—
Comprehensive loss	$ (31,651)	$ (17,391)	$ (9,141)

The accompanying notes are an integral part of these consolidated financial statements.

REPLIMUNE GROUP, INC.

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

(Amounts in thousands, except share amounts)

	Convertible preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total stockholders' equity (deficit)
	Shares	Amount	Shares	Amount				
Balances as of March 31, 2017	1,064,553	$ 31,609	4,973,439	$ 5	$ 259	$ (9,230)	$ (2,549)	$ (11,515)
Issuance of series B convertible preferred stock, net of $198 issuance costs	861,415	54,752	—	—	—	—	—	—
Issuance of common A stock	—	—	26,258	—	—	—	—	—
Foreign currency translation adjustment	—	—	—	—	—		2,376	2,376
Unrealized loss on short-term investments, net of tax	—	—	—	—	—	—	(65)	(65)
Stock options in exchange for consulting services	—	—	7,788	—	26	—	—	26
Stock-based compensation expense	—	—	—	—	812	—	—	812
Net loss	—	—	—	—	—	(19,702)	—	(19,702)
Balances as of March 31, 2018	1,925,968	86,361	5,007,485	5	1,097	(28,932)	(238)	(28,068)
Conversion of convertible preferred stock into common stock upon closing of initial public offering	(1,925,968)	(86,361)	19,157,360	19	86,342	—	—	86,361
Conversion of convertible preferred stock warrants into common stock warrants	—	—	—	—	7,094	—	—	7,094
Repurchase of class A common stock upon closing of initial public offering	—	—	(26,258)	—	—	—	—	—
Issuance of common stock upon closing of initial public offering, net of issuance costs and underwriter fees of $9,935	—	—	7,407,936	7	101,177	—	—	101,184
Stock-based compensation expense	—	—	—	—	2,730	—	—	2,730
Exercise of stock options	—	—	110,427	1	205	—	—	206
Unrealized gain on short-term investments	—	—	—	—	—	—	80	80
Foreign currency translation adjustment	—	—	—	—	—	—	(897)	(897)
Net loss	—	—	—	—	—	(30,834)	—	(30,834)
Balances as of March 31, 2019	—	$ —	31,656,950	$ 32	$ 198,645	$ (59,766)	$ (1,055)	$ 137,856

The accompanying notes are an integral part of these consolidated financial statements.

REPLIMUNE GROUP, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Amounts in thousands)

	Year Ended March 31,		
	2019	2018	2017
Cash flows from operating activities:			
Net loss	$ (30,834)	$ (19,702)	$ (7,704)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	2,730	812	208
Depreciation and amortization	148	109	122
Change in fair value of warrant liability	5,452	972	150
Stock options in exchange for consulting services	—	26	—
Net amortization of premiums and discounts on short-term investments	(1,715)	(123)	—
Non-cash rent expense	93	—	—
Changes in operating assets and liabilities:			
Research and development incentives receivable	(255)	(767)	(1,210)
Prepaid expenses and other current assets	(801)	(305)	(325)
Accounts payable	120	1,596	203
Accrued expenses and other current liabilities	(292)	1,393	1,406
Deferred rent	(24)	(25)	73
Net cash used in operating activities	(25,378)	(16,014)	(7,077)
Cash flows from investing activities:			
Purchases of property, plant and equipment	(2,600)	(136)	(238)
Purchase of short-term investments	(189,931)	(52,463)	—
Proceeds from sales and maturities of short-term investments	126,587	8,553	—
Net cash used in investing activities	(65,944)	(44,046)	(238)
Cash flows from financing activities:			
Proceeds from issuance of series A convertible preferred stock	—	—	15,000
Proceeds from issuance of series B convertible preferred stock, net of issuance costs	—	54,752	—
Proceeds from issuance of common stock in initial public offering, net of underwriting fees and discounts	103,341	—	—
Exercise of stock options	206	—	—
Payment of issuance costs	(2,157)	—	—
Net cash provided by financing activities	101,390	54,752	15,000
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(839)	2,297	(1,419)
Net increase in cash, cash equivalents and restricted cash	9,229	(3,011)	6,266
Cash, cash equivalents and restricted cash at beginning of year	17,661	20,672	14,406
Cash, cash equivalents and restricted cash at end of year	$ 26,890	$ 17,661	$ 20,672
Supplemental disclosure of non-cash investing and financing activities:			
Net unrealized gain (loss) on short term investments	$ 80	$ (65)	$ —
Purchases of property and equipment included in accounts payable	$ 5,047	$ —	$ —
Conversion of preferred stock into common stock	$ 86,361	$ —	$ —
Conversion of convertible preferred stock warrants into common stock warrants	$ 7,094	$ —	$ —
Amounts capitalized under build-to-suit lease transaction	$ 4,292	$ —	$ —

The accompanying notes are an integral part of these consolidated financial statements.

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

1. Nature of the business

Replimune Group, Inc. (the "Company") is a clinical-stage biotechnology company focused on the development of oncolytic immunotherapies to treat cancer.

Replimune Limited ("Replimune UK") was incorporated in 2015 under the laws of England, and was the sole shareholder of Replimune, Inc. ("Replimune US"), a Delaware corporation. On July 5, 2017, Replimune Group, Inc., a Delaware corporation, was incorporated and on July 10, 2017 the shareholders of Replimune UK effected a share-for-share exchange pursuant to which they exchanged their outstanding shares in Replimune UK for shares in Replimune Group, Inc., on a one-for-one basis. In addition, the holders of warrants and stock options to purchase Replimune UK capital stock canceled their warrants to purchase shares of series seed preferred stock and stock options in Replimune UK and were issued replacement warrants to purchase shares of series seed preferred stock and stock options to acquire Replimune Group, Inc. capital stock on a one-for-one basis. These transactions are collectively referred to as the reorganization. Upon completion of the reorganization, the historical consolidated financial statements of Replimune UK became the historical consolidated financial statements of Replimune Group, Inc. because the reorganization was accounted for similar to a reorganization of entities under common control due to the high degree of common ownership of Replimune UK and Replimune Group, Inc. and lack of economic substance to the transaction. The Company concluded that the reorganization resulted in no change in the material rights and preferences of each respective class of equity interests and no change in the fair value of each respective class of equity interests before and after the reorganization. On December 8, 2017, Replimune UK transferred all outstanding shares of its wholly owned subsidiary, Replimune US to Replimune Group, Inc. Replimune Group. Inc., a Delaware corporation, is the sole shareholder of Replimune UK, Replimune US and Replimune Securities Corporation, a Massachusetts corporation that was incorporated in November 2017.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance and reporting capabilities. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Forward stock split

On July 9, 2018, the Company effected a 1-for-9.94688 forward stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of the Company's Preferred Stock (see Note 7). Accordingly, all share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this forward stock split and adjustment of the preferred stock conversion ratios. Further, on July 9, 2018, the Company's authorized shares of common stock were increased to 27,314,288. Accordingly, the authorized shares of common

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

1. Nature of the business (Continued)

stock presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the newly authorized shares of common stock.

Initial public offering

On July 24, 2018, the Company completed an initial public offering ("IPO") of its common stock and issued and sold 6,700,000 shares of common stock at a public offering price of $15.00 per share, resulting in net proceeds of $93,465 after deducting underwriting discounts and commissions but before deducting offering costs of $2,157.

Upon closing of the IPO, the Company's outstanding convertible preferred stock automatically converted into shares of common stock (see Note 7). Upon conversion of the convertible preferred stock, the Company reclassified the carrying value of the convertible preferred stock to common stock and additional paid-in capital. The warrant to purchase shares of the Company's series seed convertible preferred stock was converted into a warrant to purchase shares of the Company's common stock upon the closing of the IPO. As a result, the warrant liability was remeasured a final time on the closing date of the IPO and reclassified to stockholders' equity (deficit). Additionally, the Company repurchased 26,258 shares of class A common stock at a price equal to its par value upon the closing of the IPO.

On July 30, 2018, the Company issued and sold an additional 707,936 shares of its common stock at the IPO price of $15.00 per share pursuant to the underwriters' partial exercise of their option to purchase additional shares of common stock, resulting in additional net proceeds of $9,876 after deducting discounts and commissions and other offering expenses.

Also, in connection with the completion of its IPO on July 24, 2018, the Company filed an amended and restated certificate of incorporation with the Secretary of State of the State of Delaware to authorize the issuance of up to 150,000,000 shares of common stock, par value $0.001 per share, and 10,000,000 shares of undesignated preferred stock, par value $0.001 per share.

Basis of presentation

The accompanying consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. The Company has incurred recurring losses since its inception, including net losses of $30,834, $19,702 and $7,704 for the years ended March 31, 2019, 2018 and 2017, respectively. In addition, as of March 31, 2019, the Company had an accumulated deficit of $59,766. The Company expects to continue to generate operating losses for the foreseeable future. As of June 28, 2019, the issuance date of these consolidated financial statements, the Company expects that its cash and cash equivalents and short-term investments will be sufficient to fund its operating expenses and capital expenditure requirements through at least 12 months from the issuance of the consolidated financial statements. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations.

If the Company is unable to obtain funding it could be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or it may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

1. Nature of the business (Continued)

successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

2. Summary of significant accounting policies

Principles of consolidation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, and include the accounts of the Company and its wholly owned subsidiaries, Replimune UK, Replimune US and Replimune Securities Corporation, after elimination of all intercompany accounts and transactions. The consolidated financial statements reflect the capital as if Replimune Group, Inc. had been in existence for all periods presented.

Use of estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the accrual for research and development expenses and the valuation of common stock and stock-based awards. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. Estimates are periodically reviewed in light of reasonable changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates or assumptions.

Foreign currency and currency translation

The functional currency for the Company's wholly owned foreign subsidiary, Replimune UK, is the British pound. Assets and liabilities of Replimune UK are translated into United States dollars at the exchange rate in effect on the balance sheet date. Revenues and expenses are translated at the average exchange rate in effect during the period. Unrealized translation gains and losses are recorded as a cumulative translation adjustment, which is included in the consolidated statements of convertible preferred stock and stockholders' equity (deficit) as a component of accumulated other comprehensive loss. Adjustments that arise from exchange rate changes on transactions denominated in a currency other than the local currency are included in other income (expense), net in the consolidated statements of operations as incurred.

Concentrations of credit risk and of significant suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents as well as short-term investments. The Company deposits its cash in financial institutions in amounts that may exceed federally insured limits, and has not

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. Summary of significant accounting policies (Continued)

experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company relies, and expects to continue to rely, on a small number of vendors to manufacture supplies and raw materials for its development programs. These programs could be adversely affected by a significant interruption in these manufacturing services or the availability of raw materials.

Cash and cash equivalents

The Company considers all highly liquid investments with original maturities of three months or less at date of purchase to be cash equivalents. Cash equivalents consisted of money market funds, US Treasury bonds, and US Government Agency bonds at March 31, 2019. Cash equivalents consisted of money market funds at March 31, 2018. As of March 31, 2019 and 2018, cash equivalents totaled $10,664 and $4,130, respectively.

Restricted Cash

The Company maintains certain minimum balances in segregated bank accounts in connection with its corporate credit cards and a letter of credit for the benefit of the landlords in connection with an operating lease. As of March 31, 2019 and 2018, restricted cash consisted of $0 and $78, respectively, held in connection with the Company's corporate credit cards and $1,186 and $0, respectively, held for the benefit of the landlords in connection with an operating lease. These amounts have been classified as non-current assets on the Company's consolidated balance sheets.

Short-term investments

The Company's short-term debt security investments are classified as available-for-sale and are carried at fair value, with the unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) in stockholders' equity (deficit). Realized gains and losses and declines in value determined to be other than temporary are based on the specific identification method and are included as a component of other income (expense), net in the consolidated statements of operations.

The Company evaluates its short-term debt security investments with unrealized losses for other-than-temporary impairment. When assessing short-term debt security investments for other-than-temporary declines in value, the Company considers such factors as, among other things, how significant the decline in value is as a percentage of the original cost, how long the market value of the investment has been less than its original cost, the Company's ability and intent to retain the short-term debt security investment for a period of time sufficient to allow for any anticipated recovery in fair value and market conditions in general. If any adjustment to fair value reflects a decline in the value of the short-term debt security investment that the Company considers to be "other than temporary," the Company reduces the short-term debt security investment to fair value through a charge to the consolidated statements of operations. No such adjustments were necessary during the periods presented.

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. Summary of significant accounting policies (Continued)

The Company's short-term debt security investments as of March 31, 2019 and 2018 had original maturities of less than one year.

Deferred offering costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity (deficit) as a reduction of proceeds generated as a result of the offering. Should an in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations. The Company did not record any deferred offering costs as of March 31, 2018. As of March 31, 2019, the Company recorded $2,157 of deferred offering costs in stockholders' equity (deficit) as a reduction of proceeds generated as a result of the IPO.

Property, plant and equipment

Property, plant and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the estimated useful lives of the respective assets as follows:

	Estimated Useful life
Office equipment	5 years
Computer equipment	3 years
Plant and laboratory equipment	5 years
Leasehold improvements	Lesser of lease term or 10 years

Costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated in accordance with the above guidelines once placed into service. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in loss from operations. Expenditures for repairs and maintenance are charged to expense as incurred.

Impairment of long-lived assets

Long-lived assets consist of property, plant and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. Summary of significant accounting policies (Continued)

discounted cash flows. To date, the Company has not recorded any impairment losses on long-lived assets.

Deferred rent

The Company recognizes rent expense on a straight-line basis over the respective lease terms and has recorded deferred rent for rent expense incurred but not yet paid.

Fair value measurements

Certain assets and liabilities of the Company are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's short-term investments, cash equivalents and warrant liability are carried at fair value, determined according to the fair value hierarchy described above (see Note 3). The carrying values of research and development incentives receivable, other current assets, accounts payable and accrued expenses and other current liabilities approximate their fair values due to the short-term nature of these assets and liabilities.

Warrant liability

Upon the closing of the IPO, the warrants to purchase shares of the Company's series seed convertible preferred stock were converted into warrants to purchase shares of the Company's common stock. As a result, the warrant liability was remeasured a final time on the closing date of the IPO and reclassified to stockholders' equity (deficit).

Prior to the IPO, the Company classified warrants to purchase shares of series seed preferred stock (see Note 8) as a liability on its consolidated balance sheets as these warrants to purchase shares of series seed preferred stock were free-standing financial instruments that could require the Company to transfer assets upon exercise. The warrant liability was initially recorded at fair value upon the date of the warrants' issuance and was subsequently remeasured to fair value at each reporting date. Changes

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. Summary of significant accounting policies (Continued)

in the fair value of the warrant liability were recognized as a component of total other income (expense), net in the consolidated statements of operations.

The Company utilized the Black-Scholes option-pricing model, which incorporated assumptions and estimates, to value the warrant liability. The Company assessed these assumptions and estimates on a quarterly basis as additional information impacting assumptions was obtained. Estimates and assumptions impacting the fair value measurement included the expected stock price volatility, the expected term of the warrant, the risk-free interest rate for a period that approximated the expected term of the warrant, and the Company's expected dividend yield (see Note 3).

Segment information

The Company manages its operations as a single operating segment for the purposes of assessing performance and making operating decisions. The Company's current focus is on developing oncolytic immunotherapies for the treatment of cancer.

Research and development costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries, stock-based compensation and benefits, facilities costs and laboratory supplies, depreciation and external costs of outside vendors engaged to conduct preclinical development, clinical development activities and clinical trials as well as to manufacture clinical trial materials. Non-refundable prepayments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

Research contract costs and accruals

The Company has entered into various research and development-related contracts with companies both inside and outside of the United States. These agreements are generally cancelable, and related costs are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Patent costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. Summary of significant accounting policies (Continued)

Stock-based compensation

The Company measures all stock-based awards granted to employees and directors based on the fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and the Company's expected dividend yield (see Note 10). Forfeitures are accounted for as they occur. To date, the Company has issued stock-based awards with only service-based vesting conditions and records the expense for these awards using the straight-line method.

For stock-based awards granted to consultants and non-employees, compensation expense is recognized over the shorter of the vesting period or the period during which services are rendered by such consultants and non-employees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is remeasured using the then-current fair value of the Company's common stock and updated assumption inputs in the Black-Scholes option-pricing model.

The Company classifies stock-based compensation expense in its consolidated statements of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Research and development incentives and receivable

The Company, through its subsidiary in the United Kingdom, receives reimbursements of certain research and development expenditures as part of a United Kingdom government's research and development tax reliefs program. Under the program, a percentage of qualifying research and development expenses incurred by the Company's subsidiary in the United Kingdom are reimbursed up to 14.5%.

Management has assessed the Company's research and development activities and expenditures to determine which activities and expenditures are likely to be eligible under the research and development incentive program described above. At each period end, management estimates the reimbursement available to the Company based on available information at the time.

The Company recognizes income from the research and development incentives when the relevant expenditure has been incurred, the associated conditions have been satisfied and there is reasonable assurance that the reimbursement will be received. The Company records these research and development incentives as other income. The research and development incentives receivable represents an amount due in connection with the above program. The Company recorded other income from research and development incentives of $2,528, $2,267 and $1,442 during the years ended March 31, 2019, 2018 and 2017, respectively, in the consolidated statements of operations and a research and development incentives receivable of $2,474 and $2,389 as of March 31, 2019 and 2018, respectively, on the consolidated balance sheets.

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. Summary of significant accounting policies (Continued)

Comprehensive loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. For the year ended March 31, 2019, comprehensive loss included $(897) of foreign currency translation adjustments and $80 of unrealized gains on short-term investments, net of tax. For the year ended March 31, 2018, comprehensive loss included $2,376 of foreign currency translation adjustments and $(65) of unrealized losses on short-term investments, net of tax. For the year ended March 31, 2017, comprehensive loss included $(1,437) of foreign currency translation adjustments.

Income taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Net income (loss) per share

The Company follows the two-class method when computing net income (loss) per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. Summary of significant accounting policies (Continued)

Basic net income (loss) per share attributable to common stockholders is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) attributable to common stockholders is computed by adjusting net income (loss) attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period, including potential dilutive common shares assuming the dilutive effect of common stock equivalents.

The Company's convertible preferred stock contractually entitled the holders of such shares to participate in dividends but contractually did not require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reported a net loss, such losses were not allocated to such participating securities. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Recently Adopted Accounting Pronouncements

In May 2017, the FASB issued ASU No. 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU 2017-09"), which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The standard is effective for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted. The Company adopted ASU 2017-09 as of the required effective date of April 1, 2018 and will apply to any changes to the terms or conditions of share-based payment awards prospectively. The adoption of ASU 2017-09 did not have a material impact on the Company's financial position, results of operations, or cash flows.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* ("ASU 2016-18"), which requires restricted cash to be presented with cash and cash equivalents on the consolidated statements of cash flows and disclosure of how the consolidated statements of cash flows reconciles to the balance sheet if restricted cash is shown separately from cash and cash equivalents on the balance sheet. The standard is effective for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted. The Company adopted ASU 2016-18 as of April 1, 2018. Restricted cash is now included as a component of cash, cash equivalents and restricted cash on the Company's consolidated statement of cash flows. Upon the adoption of ASU 2016-18, the amount of cash and cash equivalents previously presented on the consolidated statements of cash flows reflects the inclusion of restricted cash in the amount reported for changes in cash, cash equivalents and restricted cash. Additionally, as a result of the adoption, transfers between restricted and unrestricted cash are no longer presented as a component of the Company's investing activities. The adoption of ASU 2016-08 did not have a material impact on the Company's financial position, results of operations, or cash flows. On the statement of

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. Summary of significant accounting policies (Continued)

cash flows for the years ended March 31, 2018 and 2017, the Company reclassified restricted cash of $78 and $75, respectively, to be included in *Cash, cash equivalents and restricted cash at beginning of year* and *Cash, cash equivalents and restricted cash at end of year*.

In October 2016, the FASB issued ASU No. 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfer of Assets Other than Inventory* ("ASU 2016-16"), which requires the recognition of the income tax consequences of an intra-entity transfer of an asset, other than inventory, when the transfer occurs. The standard is effective for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. The Company adopted ASU 2016-16 as of the required effective date of April 1, 2018. The adoption of ASU 2016-16 did not have a material impact on the Company's financial position, results of operations or cash flows.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"), to address diversity in practice in how certain cash receipts and cash payments are presented and classified in the consolidated statements of cash flows. The standard is effective for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. The Company adopted ASU 2016-16 as of the required effective date of April 1, 2018. The adoption of ASU 2016-15 did not have a material impact on the Company's financial position, results of operations or cash flows.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606) ("ASU 2014-09"), which supersedes existing revenue recognition guidance under GAAP. The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The standard defines a five-step process to achieve this principle, and will require companies to use more judgment and make more estimates than under the current guidance. The Company expects that these judgments and estimates will include identifying performance obligations in the customer contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. In August 2015, the FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers* (Topic 606): Deferral of the Effective Date, which delays the effective date of ASU 2014-09 such that the standard is effective for public entities for annual periods beginning after December 15, 2017 and for interim periods within those fiscal years. Early adoption of the standard is permitted for annual periods beginning after December 15, 2016. The Company adopted ASU 2014-09 on a full retrospective basis effective April 1, 2018. The adoption of ASU 2014-09 did not have an impact on the Company's consolidated financial statements as the Company does not currently have any revenue-generating arrangements.

Recently Issued Accounting Pronouncements

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606* ("ASU2018-18"), which clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in Topic 606 should be applied, including recognition,

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. Summary of significant accounting policies (Continued)

measurement, presentation, and disclosure requirements. The standard adds unit-of-account guidance in Topic 808 to align with the guidance in Topic 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of Topic 606, and requires that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under Topic 606 is precluded if the collaborative arrangement participant is not a customer. The standard is effective for interim and annual periods beginning after December 15, 2019, with early adoption permitted, including adoption in any interim period for public business entities for periods in which financial statements have not been issued. Amendments in the standard should be applied retrospectively to the date of initial application of Topic 606, but entities may elect to apply the amendments in this Update retrospectively either to all contracts or only to contracts that are not completed at the date of initial application of Topic 606, and should disclose the election. An entity may also elect to apply the practical expedient for contract modifications that is permitted for entities using the modified retrospective transition method in Topic 606. The Company is in the process of evaluating the impact of ASU 2018-18 on its consolidated financial statements and disclosures.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820), Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"). The amendments in this ASU require certain existing disclosure requirements in Topic 820 to be modified or removed, and certain new disclosure requirements to be added to the Topic. In addition, this ASU allows entities to exercise more discretion when considering fair value measurement disclosures. ASU 2018-13 is effective after December 15, 2019 with early adoption permitted. The Company is in the process of evaluating the impact of ASU 2018-13 on its consolidated financial statements and disclosures.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718)*: *Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. ASU 2018-07 also clarifies that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Revenue from Contracts with Customers (Topic 606). The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted. The Company is currently assessing the effect that ASU 2018-07 will have on its consolidated financial statements and disclosures.

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815) I. Accounting for Certain Financial Instruments with Down Round Features II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception* ("ASU 2017-11"). Part I applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down-round features. Part II replaces the indefinite deferral for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of nonpublic entities contained within Accounting Standards Codification ("ASC") Topic 480 with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. ASU 2017-11 is required

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. Summary of significant accounting policies (Continued)

to be adopted for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. The adoption of ASU 2017-11 is not expected to have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, which supersedes FASB Topic 840, *Leases (Topic 840)* and provides principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases. In January 2018, the FASB issued ASU No. 2018-01, *Leases (Topic 842): Land Easement Practical Expedient for Transition to Topic 842*, which amends ASU 2016-02 to provide entities an optional transition practical expedient to not evaluate under Topic 842 existing or expired land easements that were not previously accounted for as leases under the current leases guidance in Topic 842. An entity that elects this practical expedient should evaluate new or modified land easements under Topic 842 beginning at the date that the entity adopts Topic 842. In July 2018, the FASB also issued ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, which provides an optional transition method that allows entities to elect to apply the standard prospectively at its effective date, versus recasting the prior periods presented. The standard will be effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted upon issuance. The Company expects to elect the option to not restate comparative periods presented in the financial statements, using a cumulative-effect adjustment on the effective date of the standard, with comparative periods presented in accordance with the existing guidance in ASC 840. The Company will adopt the new standard effective April 1, 2019 and will use the effective date as the date of initial application.

The Company currently expects to elect the available package of practical expedients which allows the Company to not reassess previous accounting conclusions around whether arrangements are or contain leases, the classification of leases, and the treatment of initial direct costs. The Company also expects it will make an accounting policy election to utilize the short-term lease exemption, whereby leases with a term of twelve months or less will not follow the recognition and measurement requirements of the new standard.

The Company is currently evaluating the impact of pending adoption on its consolidated financial statements and disclosures, including the impact on the Company's build-to-suit lease for which the accounting may change under Topic 842.

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

3. Fair value of financial assets and liabilities

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis:

	Fair Value Measurements as of March 31, 2019 Using:			
	Level 1	Level 2	Level 3	Total
Assets				
Money market funds	$ —	$ 2,676	$ —	$ 2,676
Commercial paper	—	46,687	—	46,687
US Government Agency bonds	—	20,884	—	20,884
US Treasury bonds	—	41,057	—	41,057
Corporate debt securities	—	8,467	—	8,467
	$ —	$ 119,771	$ —	$ 119,771

	Fair Value Measurements as of March 31, 2018 Using:			
	Level 1	Level 2	Level 3	Total
Assets				
Money market funds	$ —	$ 4,130	$ —	$ 4,130
Commercial paper	—	27,998	—	27,998
Corporate debt securities	—	15,970	—	15,970
	$ —	$ 48,098	$ —	$ 48,098
Liabilities:				
Warrant liability	$ —	$ —	$ 1,642	$ 1,642
	$ —	$ —	$ 1,642	$ 1,642

During the years ended March 31, 2019 and 2018, there were no transfers between levels.

Valuation of cash equivalents and short-term investments

Money market funds, commercial paper, US Treasury bonds, US Government Agency bonds and corporate debt securities were valued by the Company using quoted prices in active markets for similar securities, which represent a Level 2 measurement within the fair value hierarchy.

Valuation of Warrant Liability

The warrant liability is related to the warrants to purchase shares of series seed preferred stock (see Note 8). The fair value of the warrant liability was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. Upon the closing of the IPO in July 2018, the warrant to purchase shares of the Company's series seed convertible preferred stock was converted into a warrant to purchase shares of the Company's common stock. As a result, the warrant liability was remeasured a final time on the closing date of the IPO and reclassified to stockholders' equity (deficit).

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

3. Fair value of financial assets and liabilities (Continued)

The Company used the Black-Scholes option-pricing model, which incorporated assumptions and estimates, to value the warrant liability. Key estimates and assumptions impacting the fair value measurement include (i) the expected term of the warrants, (ii) the risk-free interest rate, (iii) the expected dividend yield, (iv) expected volatility of the price of the underlying series seed preferred stock and (v) the fair value of the series seed preferred stock on the valuation date. The Company estimated the fair value per share of the underlying series seed preferred stock based, in part, on the results of third-party valuations and additional factors deemed relevant. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. The Company estimated a 0% expected dividend yield based on the fact that the Company has never paid or declared dividends and does not intend to do so in the foreseeable future. Prior to July 2018, the Company was a private company and accordingly, lacked company-specific historical and implied volatility information of its stock, the expected stock volatility was based on the historical volatility of publicly traded peer companies for a term equal to the remaining expected term of the warrants.

As of March 31, 2018, the warrant liability was valued at $1,642 and classified as a non-current liability on the consolidated balance sheet. The following assumptions were used in valuing the warrant liability:

	March 31, 2018
Risk-free interest rate	2.69%
Expected term (in years)	7.5
Expected volatility	65.8%
Expected dividend yield	0%

Based on the terms and conditions of the warrant, upon closing of the Company's IPO in July 2018, the warrant to purchase shares of the Company's series seed convertible preferred stock was converted into a warrant to purchase shares of the Company's common stock. On that date, the Company remeasured the warrant liability to fair value and reclassified the total carrying value to additional paid-in capital. The Company performed the final remeasurement of the warrant liability using the IPO price of $15.00 per share and recorded the change in fair value as a component of total other income (expense), net in the consolidated statement of operations.

The following assumptions were used to measure the fair market value of the warrant liability upon the conversion date:

Risk-free interest rate	2.81%
Expected term (in years)	7.2
Expected volatility	64.4%
Expected dividend yield	0%

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

3. Fair value of financial assets and liabilities (Continued)

The following table presents a roll forward of the warrant liability:

	Warrant Liability
Balance at March 31, 2018	$ 1,642
Change in fair value	5,452
Conversion of convertible preferred stock warrant into common stock warrant	(7,094)
Balance at March 31, 2019	$ —

4. Short-term investments

Short-term investments by investment type consisted of the following:

	March 31, 2019			
	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
Commercial paper	$ 46,687	$ 2	$ (2)	$ 46,687
US Government agency bonds	15,889	4	—	15,893
US Treasury bonds	38,047	13	—	38,060
Corporate debt securities	8,469	—	(2)	8,467
	$ 109,092	$ 19	$ (4)	$ 109,107

	March 31, 2018			
	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
Commercial paper	$ 28,028	$ 2	$ (32)	$ 27,998
Corporate debt securities	16,005	—	(35)	15,970
	$ 44,033	$ 2	$ (67)	$ 43,968

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

5. Property, plant and equipment, net

Property, plant and equipment, net consisted of the following:

	March 31, 2019	March 31, 2018
Leasehold improvements	$ 154	$ 154
Construction in progress	124	—
Build-to-suit lease asset	11,514	—
Office equipment	49	49
Computer equipment	138	87
Plant and laboratory equipment	584	336
	$ 12,563	$ 626
Less: Accumulated depreciation and amortization	(404)	(256)
	$ 12,159	$ 370

Depreciation and amortization expense was $148, $109 and $122 for the years ended March 31, 2019, 2018 and 2017, respectively, and recorded within research and development and general and administrative expenses in the consolidated statement of operations.

Build-to-suit lease asset, as of March 31, 2019, includes $11,514 capitalized in connection with the Company's build-to-suit lease accounting (see Note 13).

6. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following:

	March 31, 2019	March 31, 2018
Accrued research and development costs	$ 530	$ 949
Accrued compensation and benefits costs	1,510	949
Accrued professional fees	464	1,094
Deferred rent	24	26
Other	273	153
	$ 2,801	$ 3,171

7. Convertible preferred stock

The Company previously issued series seed convertible preferred stock (the "series seed preferred stock"), series A convertible preferred stock (the "series A preferred stock") and series B convertible preferred stock (the "series B preferred stock"). The series seed preferred stock, series A preferred stock and series B preferred stock are collectively referred to as the "preferred stock." In connection with the closing of the IPO, the preferred stock converted into 19,157,360 shares of common stock on a 1:9.94688 basis. There was no preferred stock outstanding as of March 31, 2019.

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

7. Convertible preferred stock (Continued)

As of March 31, 2018, preferred stock consisted of the following (in thousands, except share amounts):

	March 31, 2018				
	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series seed preferred stock	250,000	200,000	$ 1,609	$ 2,000	1,989,376
Series A preferred stock	864,553	864,553	30,000	30,000	8,599,601
Series B preferred stock	861,415	861,415	54,752	54,950	8,568,383
	1,975,968	1,925,968	$ 86,361	$ 86,950	19,157,360

Prior to the closing of the IPO, the holders of the preferred stock had the following rights and preferences:

The holders of the Preferred Stock have the following rights and preferences:

Voting

The holders of the preferred stock were entitled to vote, together with the holders of common stock, on all matters submitted to the stockholders for a vote and were entitled to the number of votes equal to the number of whole shares of common stock into which such holders of preferred stock could convert on the record date of for determination of stockholders entitled to vote. The holders of preferred stock and common stock, voting as a single class, were entitled to elect two directors of the Company. Additionally, the holders of the series seed preferred stock were entitled to elect two directors of the Company, the holders of the series A preferred stock were entitled to elect one director of the Company and the holders of at least 55% of the outstanding series B preferred stock were entitled to elect two directors of the Company.

Conversion

Each share of preferred stock was convertible into common stock, at any time, at the option of the holder, and without the payment of additional consideration, at the applicable conversion ratio then in effect for each series of preferred stock and subject to adjustment in accordance with anti-dilution provisions. In addition, each share of preferred stock was convertible into common stock at the applicable conversion ratio then in effect for each series of preferred stock upon the earlier of (i) the closing of a firm commitment underwritten public offering of the Company's common stock with gross proceeds to the Company of at least $30,000 and at a price per share of not less than $9.62, subject to appropriate adjustment in the event of any stock split, stock dividend, combination or other similar recapitalization, or (ii) a date specified by vote or written consent of the holders of 75% of the outstanding preferred stock (voting together as a single class on an as-converted basis). For any events of deemed liquidation (as defined below) in which series B preferred stock investors would receive less than their full liquidation preference, a further approval of holders of 55% of the outstanding series B preferred stock was required. As of March 31, 2018, each share of preferred stock was convertible into 9.94688 share of common stock.

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

7. Convertible preferred stock (Continued)

The conversion ratio for each series of preferred stock was determined by dividing the original issue price of each series of preferred stock by the conversion price of each series (as defined below). As of March 31, 2018, the series seed preferred stock original issue price and series seed preferred stock conversion price were $1.01 per share and $10.00 per share, respectively. As of March 31, 2018, the series A preferred stock original issue price and series A preferred stock conversion price were $3.49 per share and $34.70 per share, respectively. As of March 31, 2018, the series B preferred stock original issue price and series B preferred stock conversion price were $6.41 per share and $63.79 per share, respectively. Such series seed preferred stock original issue price, series A preferred stock original issue price and series B preferred stock original issue price and series seed preferred stock conversion price, series A preferred stock conversion price and series B preferred stock conversion price, and the rate at which each series of preferred stock may be converted into common stock, were subject to appropriate adjustment from time to time in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the preferred stock. The series seed preferred stock conversion price, series A preferred stock conversion price and series B preferred stock conversion price were also subject to adjustments based on weighted-average anti-dilution provisions set forth in the Company's certificate of incorporation, as amended and restated, in the event that additional securities were issued at a purchase price less than the series seed preferred stock conversion price, series A preferred stock conversion price or series B preferred stock conversion price then in effect.

Dividends

The holders of the preferred stock were entitled to be paid noncumulative dividends if and when declared by the Company's board of directors. The Company could not pay any dividends on shares of common stock of the Company unless the holders of preferred stock then outstanding simultaneously receive dividends at the same rate and same time as dividends paid with respect to common stock. Dividends were to accrue on a daily basis assuming a 365-day year, and were to be paid in cash. Through the date of the IPO, when preferred shares converted to common shares, no dividends had been declared or paid.

Liquidation preference

In the event of any voluntary or involuntary liquidation event, dissolution, winding up of the Company or an event of deemed liquidation, each holder of the then outstanding series B preferred stock would have been entitled to receive, prior and in preference to any distributions to the holders of series A preferred stock, series seed preferred stock and common stock, an amount equal to the greater of (i) the applicable original issue price, plus any declared but unpaid dividends thereon, or (ii) the amount such holder would have received if such holder had converted its shares into common stock immediately prior to such liquidation event.

After the payment of all preferential amounts to the holders of series B preferred stock, each holder of the then outstanding series A preferred stock would have been entitled to receive, prior and in preference to any distributions to the holders of series seed preferred stock and common stock, an amount equal to the greater of (i) the applicable original issue price, plus any declared but unpaid

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

7. Convertible preferred stock (Continued)

dividends thereon, or (ii) the amount such holder would have received if such holder had converted its shares into common stock immediately prior to such liquidation event.

After the payment of all preferential amounts to the holders of series A preferred stock, each holder of the then outstanding series seed preferred stock would have been entitled to receive, prior and in preference to any distributions to the holders of common stock, an amount equal to the greater of (i) the applicable original issue price, plus any declared but unpaid dividends thereon or (ii) the amount such holder would have received if such holder had converted its shares into common stock immediately prior to such liquidation event.

After payments have been made in full to the holders of preferred stock, then, to the extent available, the remaining amounts would have been distributed among the holders of the shares of common stock, the holders of series B preferred stock and the holders of series A preferred stock, pro rata based on the number of shares held by each holder, assuming full conversion of all such preferred stock.

The holders of series B preferred stock and series A preferred stock were subject to a participation cap (as defined below) for remaining amounts that would have been distributed, which was $127.58 per share for the series B preferred stock and $69.40 per share for the series A preferred stock.

To the extent available, the remaining amounts greater than the total of the participation caps would have been distributed among the holders of the shares of common stock, pro rata based on the number of shares held by each holder.

Unless a majority of the holders of the then outstanding preferred stock, on an as-if-converted basis voting together as a single class, elect otherwise, an event of deemed liquidation shall include a merger or consolidation (other than one in which stockholders of the Company own a majority by voting power of the outstanding shares of the surviving or acquiring corporation), sale, transfer or exclusive license of substantially all of the assets of the Company. The preferred stock was conditionally redeemable upon an event of deemed liquidation, which was defined as any (i) merger, consolidation or acquisition, involving the Company or its Subsidiary Undertaking, in which the Company or its subsidiary undertaking was not the surviving entity, (ii) an asset sale, (iii) a share sale, (iv) an initial public offering, (v) the occurrence of a change of control in respect of the Company, (vi) a winding up (vii) or any other a return of capital to stockholders (other than a conversion, redemption or repurchase of shares made in accordance with the applicable governing documents).

Redemption

The Company's certificate of incorporation, as amended and restated, did not provide redemption rights to the holders of preferred stock.

The holders of shares of convertible preferred stock had liquidation rights in the event of a deemed liquidation that, in certain situations, were not solely within the control of the Company. Therefore, convertible preferred stock was classified outside of stockholders' equity (deficit).

Upon issuance of each class of preferred stock, the Company assessed the embedded conversion and liquidation features of the securities. The Company determined that each class of preferred stock did not require the Company to separately account for the liquidation features. The Company also

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

7. Convertible preferred stock (Continued)

concluded that no beneficial conversion feature existed upon the issuance date of the series A preferred stock or series B preferred stock as of March 31, 2018. However, the Company did conclude that a beneficial conversion feature existed upon the issuance date of the series seed preferred stock. As the series seed preferred stock was convertible into common stock, at any time, at the option of the holder, and without the payment of additional consideration, at the applicable conversion ratio then in effect, the Company recognized the accretion of the beneficial conversion feature as a deemed dividend immediately upon the issuance of the series seed preferred stock.

8. Preferred stock warrants

In connection with the issuance of the series seed preferred stock, the Company issued to the holders of the series seed preferred stock warrants for the purchase of 50,000 shares of series seed preferred stock, which became fully vested and exercisable in the year of issuance. The warrants to purchase shares of series seed preferred stock were issued at an exercise price of $10.00 per share and expire on the earlier of September 16, 2025 or a qualified change of control event.

The issuance date fair value of the warrants to purchase shares of series seed preferred stock was $391 and was recorded as a liability with a corresponding reduction in the carrying value of the series seed preferred stock. As of March 31, 2019 and 2018, the fair value of the warrant liability was $0 and $1,642, respectively. The Company recognized a loss of $5,452, $972 and $150 within total other income (expense), net in the consolidated statements of operations for the years ended March 31, 2019, 2018 and 2017, respectively, related to the change in fair value of the warrant liability.

Upon the closing of the Company's IPO in July 2018, all outstanding preferred stock was converted into common stock and the series seed preferred stock warrants became exercisable for common stock instead of series seed preferred stock. As a result, the warrant liability was remeasured a final time on the closing date of the IPO and reclassified to stockholders' equity (deficit).

9. Stockholders' Equity

Common Stock

As of March 31, 2019, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue up to 150,000,000 shares of common stock, par value $0.001 per share. As of March 31, 2018, the Company was authorized to issue 27,314,288 shares of par value $0.001 per share common stock (including 26,258 authorized shares of common A stock). In July 2017, the Company issued and sold 26,258 shares of par value $0.001 per share common A stock for nominal cash proceeds. In July 2018, the Company repurchased 26,258 shares of par value $0.001 per share common A stock for nominal cash proceeds. The voting, dividend and liquidation rights of the holders of the Company's common stock is subject to and qualified by the rights, powers and preferences of the holders of the preferred stock as set forth above.

As of March 31, 2019, the Company had reserved 6,873,744 shares of common stock for the exercise of outstanding stock options, the number of shares remaining available for grant under the Company's 2018 Omnibus Incentive Compensation Plan and the Company's Employee Stock Purchase Plan (see Note 10) and the exercise of the outstanding warrants to purchase shares of common. As of March 31, 2018, the Company had reserved 22,306,801 shares of common stock for the conversion of

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

9. Stockholders' Equity (Continued)

outstanding shares of preferred stock (see Note 7), the exercise of outstanding stock options, the number of shares remaining available for grant under the Company's 2017 Equity Compensation Plan (see Note 10) and the exercise of the outstanding warrants to purchase shares of series seed preferred stock (see Note 8), assuming all warrants to purchase shares of series seed preferred stock became warrants to purchase shares of common stock at the applicable conversion ratio.

Voting

Each share of common stock, including common A stock, entitles the holder to one vote, together with the holders of preferred stock, on all matters submitted to the stockholders for a vote. The holders of common stock, together with the holders of preferred stock and voting as a single class, are entitled to elect two directors of the Company by vote of a majority of such shares.

Dividends

Common stockholders are entitled to receive dividends, as may be declared by the Company's board of directors, if any, subject to the preferential dividend rights of the preferred stock. Through March 31, 2019, no cash dividends have been declared or paid.

Each share of common A stock is entitled to receive dividends, as may be declared by the Company's board of directors, if any, equal to a maximum of 100% of each share's par value. Upon an event of deemed liquidation, common A stock is entitled to receive dividends equal to a maximum of 300% of each share's par value.

Undesignated Preferred Stock

As of March 31, 2019, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue up to 10,000,000 shares of undesignated preferred stock, par value $0.001 per share. There were no undesignated preferred shares issued or outstanding as of March 31, 2019.

10. Stock-Based Compensation

2015 Enterprise Management Incentive Share Option Plan

The 2015 Enterprise Management Incentive Share Option Plan of Replimune UK (the "2015 Plan") provided for Replimune UK to grant incentive stock options, non-statutory stock options, stock awards, stock units, stock appreciation rights and other stock-based awards. Incentive stock options are granted only to the Company's employees, including officers and directors who are also employees. Non-statutory stock options are granted to employees, members of the board of directors, outside advisors and consultants of the Company.

2017 Equity Compensation Plan

In July 2017, in conjunction with the Reorganization, the 2015 Plan was terminated, and all awards were cancelled with replacement awards issued under the 2017 Equity Compensation Plan (the "2017 Plan"). Subsequent to the Reorganization, no additional grants will be made under the 2015 Plan and

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

10. Stock-Based Compensation (Continued)

any outstanding awards under the 2015 Plan will continue with their original terms. The Company concluded that the cancellation of the 2015 Plan and issuance of replacement awards under the 2017 Plan was a modification with no change in the material rights and preferences and therefore no recorded change in the fair value of each respective award.

The Company's 2017 Plan provides for the Company to grant incentive stock options or non-statutory stock options, stock awards, stock units, stock appreciation rights and other stock-based awards. Incentive stock options may be granted only to the Company's employees, including officers and directors who are also employees. Restricted stock awards and non-statutory stock options may be granted to employees, officers, members of the board of directors, advisors and consultants of the Company. The maximum number of common shares that may be issued under the 2017 Plan was 2,659,885 as of March 31, 2019, of which 0 remained available for future grants as of March 31, 2019. Shares with respect to which awards have expired, terminated, surrendered or cancelled under the 2017 Plan without having been fully exercised will be available for future awards under the 2017 Plan. In addition, shares of common stock that are tendered to the Company by a participant to exercise an award are added to the number of shares of common stock available for the grant of awards.

2018 Omnibus Incentive Compensation Plan

On July 9, 2018, the Company's board of directors adopted, and the Company's stockholders approved the 2018 Omnibus Incentive Compensation Plan (the "2018 Plan"), which became effective immediately prior to the effectiveness of the registration statement for the Company's initial public offering. The 2018 Plan provides for the issuance of incentive stock options, non-qualified stock options, stock awards, stock units, stock appreciation rights and other stock-based awards. The number of shares initially reserved for issuance under the 2018 Plan is 3,617,968 shares. If any options or stock appreciation rights, including outstanding options and stock appreciation rights granted under the 2017 Plan (up to 2,520,247 shares), terminate, expire, or are canceled, forfeited, exchanged, or surrendered without having been exercised, or if any stock awards, stock units or other stock-based awards, including outstanding awards granted under the 2017 Plan, are forfeited, terminated, or otherwise not paid in full in shares of common stock, the shares of the Company's common stock subject to such grants will be available for purposes of our 2018 Plan. As of March 31, 2019, 2,306,004 shares remained available for future grants under the 2018 Plan.

The 2015 Plan, the 2017 Plan and the 2018 Plan was administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. However, the board of directors shall administer and approve all grants made to non-employee directors. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, except that the exercise price per share of incentive stock options may not be less than 100% of the fair market value of the common stock on the date of grant (or 110% of fair value in the case of an award granted to employees who hold more than 10% of the total combined voting power of all classes of stock at the time of grant) and the term of stock options may not be greater than five years for an incentive stock option granted to a 10% stockholder and greater than ten years for all other options granted. Stock options awarded under both plans expire ten years after the grant date, unless the board of directors sets a shorter term. Vesting periods for both plans are determined at the discretion of the board of directors. Incentive stock options granted to employees and non-statutory options granted to

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

10. Stock-Based Compensation (Continued)

employees, officers, members of the board of directors, advisors, and consultants of the Company typically vest over four years.

Employee Stock Purchase Plan

On July 9, 2018, the Company's board of directors adopted and the Company's stockholders approved the Employee Stock Purchase Plan (the "ESPP"), which became effective immediately prior to the effectiveness of the registration statement for the Company's initial public offering. The total shares of common stock initially reserved for issuance under the ESPP is limited to 348,612 shares. In addition, as of the first trading day of each fiscal year during the term of the ESPP (excluding any extensions), an additional number of shares of the Company's common stock equal to 1% of the total number of shares outstanding on the last trading day in the immediately preceding fiscal year or 697,224 shares, whichever is less (or such lesser amount as determined by the Company's board of directors) will be added to the number of shares authorized under the ESPP. If the total number of shares of common stock to be purchased pursuant to outstanding purchase rights on any particular date exceed the number of shares then available for issuance under the ESPP, then the plan administrator will allocate the available shares pro-rata and refund any excess payroll deductions or other contributions to participants.

The following table presents, on a weighted-average basis, the assumptions that the Company used to determine the grant-date fair value of stock options granted to employees and directors:

	Year Ended March 31,		
	2019	2018	2017
Risk-free interest rate	2.81%	2.01%	1.67%
Expected term (in years)	6.1	6.0	6.0
Expected volatility	62.0%	75.0%	75.0%
Expected dividend yield	0%	0%	0%

The following table presents the assumptions that the Company used to determine the grant-date fair value of stock options granted to a non-employee:

	Year Ended March 31,
	2018
Risk-free interest rate	2.29%
Expected term (in years)	10.0
Expected volatility	75.0%
Expected dividend yield	0%

All outstanding non-employee options granted during the year ended March 31, 2018 have vested, and there were no options granted to non-employees during the year ended March 31, 2019 or 2017.

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

10. Stock-Based Compensation (Continued)

Stock option valuation

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model. The Company lacks company-specific historical and implied volatility information. Therefore, it estimated its expected stock volatility based on the historical volatility of a publicly traded set of peer companies. For options with service-based vesting conditions, the expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

Stock options

The following table summarizes the Company's stock option activity:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of March 31, 2018	2,520,247	$ 2.72	8.91	$ 2,808
Granted	1,371,500	14.92	9.78	
Exercised	(110,427)	1.87		
Cancelled	(59,536)	8.65		
Outstanding as of March 31, 2019	3,721,784	$ 7.14	8.61	$ 30,150
Options exercisable as of March 31, 2018	592,349	$ 1.84	8.22	$ 1,184
Options exercisable as of March 31, 2019	1,278,330	$ 2.51	7.75	$ 16,249

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock.

The weighted average grant-date fair value per share of stock options granted during the years ended March 31, 2019 and 2018 was $8.82 and $1.92, respectively.

The total fair value of options vested during the years ended March 31, 2019 and 2018 was $1,298 and $398, respectively.

As of March 31, 2019, there were no outstanding unvested service-based stock options held by non-employees.

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

10. Stock-Based Compensation (Continued)

Stock-Based Compensation Expense

Stock-based compensation expense was classified in the consolidated statements of operations as follows:

	Year Ended March 31,		
	2019	2018	2017
Research and development	$ 1,488	$ 335	$ 65
General and administrative	1,242	477	143
	$ 2,730	$ 812	$ 208

As of March 31, 2019, total unrecognized compensation cost related to the unvested stock-based awards was $11,807, which is expected to be recognized over a weighted average period of 2.36 years.

11. Net loss per share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	Year Ended March 31,		
	2019	2018	2017
Numerator:			
Net loss attributable to common stockholders	$ (30,834)	$ (19,702)	$ (7,704)
Denominator:			
Weighted average common shares outstanding, basic and diluted	23,198,400	4,978,539	4,973,439
Net loss per share attributable to common stockholders, basic and diluted	$ (1.33)	$ (3.96)	$ (1.55)

The Company's potentially dilutive securities, which include stock options, preferred stock and warrants to purchase shares of series seed preferred stock, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Common A stock has been excluded from the computation of diluted net loss per share because the shares have nominal economic participation rights. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

11. Net loss per share (Continued)

common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Year Ended March 31,		
	2019	2018	2017
Options to purchase common stock	3,721,784	2,520,247	930,027
Convertible preferred stock (as converted to common stock)	—	19,157,360	10,588,977
Warrants to purchase convertible preferred stock (as converted to common stock)	497,344	497,344	497,344
	4,219,128	22,174,951	12,016,348

12. Significant agreements

Agreement with Bristol-Myers Squibb Company

In February 2018, the Company entered into an agreement with Bristol-Myers Squibb Company ("BMS"). Pursuant to the agreement, BMS will provide to the Company, at no cost, a compound for use in the Company's ongoing clinical trial. Under the agreement, the Company will sponsor, fund and conduct the clinical trial in accordance with an agreed-upon protocol. BMS granted the Company a non-exclusive, non-transferrable, royalty-free license (with a right to sublicense) under its intellectual property to its compound in the clinical trial and agreed to supply its compound, at its cost and for no charge to the Company, for use in the clinical trial.

Unless earlier terminated, the agreement will remain in effect until (i) the completion of the clinical trial, (ii) all related clinical trial data have been delivered to both parties and (iii) the completion of any statistical analyses and bioanalyses contemplated by the clinical trial protocol or any analysis otherwise agreed upon by the parties. The agreement may be terminated by either party (i) in the event of an uncured material breach by the other party, (ii) in the event the other party is insolvent or in bankruptcy proceedings or (iii) for safety reasons. Upon termination, the licenses granted to the Company to use BMS's compound in the clinical trial will terminate.

As of March 31, 2019, the Company had not incurred any costs and does not expect to incur future costs in connection with this agreement.

Agreement with Regeneron Pharmaceuticals, Inc.

In May 2018, the Company entered into an agreement with Regeneron Pharmaceuticals, Inc. ("Regeneron"). The Company and Regeneron are each independently developing compounds for the treatment of certain tumor types. Pursuant to the agreement, the Company and Regeneron will undertake one or more clinical trials using a combination of the compounds being developed by each entity. Under the agreement, each study will be conducted under terms set out in a separately agreed upon study plan that will identify the name of the sponsor and which party will manage the particular clinical trial, and include the protocol, the budget and a schedule of clinical obligations. In June 2018, under the terms of the agreement between the Company and Regeneron, the parties agreed to the first study plan. The Company and Regeneron have agreed to the protocol, budget, sample testing and

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

12. Significant agreements (Continued)

clinical obligations schedule under the study plan. Development and supply costs associated with the study plan will be split equally between the Company and Regeneron.

Pursuant to the terms of the agreement, each party granted the other party a non-exclusive license under its respective intellectual property and agreed to contribute the necessary resources needed to fulfill its respective obligations, in each case, under the terms of the agreed-upon or to-be agreed upon study plans. Development costs of a particular clinical trial will be split equally between the Company and Regeneron.

The agreement may be terminated by either party if (i) there is no active study plan for which a final study report has not been completed, (ii) the parties have not entered into a study plan for an additional clinical trial within a period of time after the delivery of the most recent final study report or (iii) in the event of a material breach.

The Company will account for costs incurred as part of the study, including costs to supply compounds for use in the study, as research and development expenses within the consolidated statement of operations. The Company will recognize any amounts received from Regeneron in connection with this agreement as an offset to research and development expense within the consolidated statement of operations.

Under the terms of the agreement, on a quarterly basis the Company and Regeneron true-up costs of the study and make corresponding payments to the party that incurred the majority of the costs. During the year ended March 31, 2019, the Company did not receive or make any payments under the terms of the agreement to Regeneron. As of March 31, 2019, the Company recorded $337 of receivables from Regeneron in connection with this agreement in prepaid expenses and other current assets in the consolidated balance sheet.

13. Commitments and contingencies

Lease agreements

In December 2015, the Company entered into a lease agreement for office space in Woburn, Massachusetts, which expires on March 30, 2021. The Company has the option to extend the lease agreement for successive periods of five years. Monthly lease payments, inclusive of base rent and ancillary charges, total $7. Monthly base rent is subject to increase each year in proportion to the Consumer Price Index.

In April 2016, the Company entered into a lease agreement for office and laboratory space in Abingdon, England, which expires on April 3, 2026. The Company has the right to terminate the lease as of April 4, 2021 upon at least nine months' prior written notice. Monthly lease payments are inclusive of base rent, ancillary charges, non-rent shared tenant occupancy costs and the respective value added tax to be paid. Monthly lease payments include base rent of approximately $23 through December 3, 2016 and $31 thereafter. Monthly base rent is subject to increase after April 2021 in proportion to the Retail Price Index.

Build-to-suit lease

In June 2018, the Company entered into an agreement to lease approximately 63,000 square feet of office, manufacturing and laboratory space within a previously occupied building with approximately

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

13. Commitments and contingencies (Continued)

106,000 square feet of rentable space in Framingham, Massachusetts. Pursuant to the lease agreement, the lease term commenced in November 2018, subject to the landlord completing certain agreed upon landlord improvements. The rent commencement date is estimated to be August 2019. The initial lease term is ten years from the rent commencement date and includes two optional five year extensions. Annual lease payments during the first year are $2,373 with increases of 3.0% each year.

The Company is not the legal owner of the leased space. However, in accordance with ASC 840, Leases, the Company is deemed to be the owner of the leased space during the construction period because of certain indemnification provisions within the lease agreement. As a result, as of March 31, 2019, the Company capitalized $4,993 (equal to the estimated fair value of its leased portion of the premises) as build-to-suit lease asset within property and equipment. The Company has engaged a third party to develop the leased space to the Company's specifications as office, manufacturing and laboratory space. The Company has capitalized costs of construction of $6,521 to build-to-suit lease asset within property, plant and equipment on its consolidated balance sheet. Of the $6,521 of capitalized costs, $1,474 had been paid, $5,047 remained payable and $2,174 was reimbursable by the landlord as of March 31, 2019. The construction is expected to be completed in September 2019, at which time the Company will assess and determine if the assets and corresponding liability should be de-recognized.

The Company recorded the following for the lease agreement for its new office, manufacturing and laboratory space during the construction period:

	Year Ended March 31, 2019
Rent expense	$ 556
Amounts capitalized as build-to-suit lease	$ 11,514

The Company recorded total rent expense of $556, $430 and $282 during the years ended March 31, 2019, 2018 and 2017, respectively, and recorded within research and development and general and administrative expenses in the consolidated statement of operations. Rent expense for the year ended March 31, 2019 included $93 of ground rent associated with the build-to-suit lease.

The following table summarizes the future minimum lease payments due under the Company's operating leases as of March 31, 2019:

2020	$ 2,062
2021	2,901
2022	2,493
2023	2,568
2024	2,645
2025	2,725
Thereafter	12,770
	$ 28,164

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

13. Commitments and contingencies (Continued)

Manufacturing commitments

The Company has entered into an agreement with a contract manufacturing organization to provide clinical trial products. As of March 31, 2019, the Company had committed to minimum payments under these arrangements totaling $4,694 through March 31, 2020. As of March 31, 2018, the Company had committed to minimum payments under these arrangements totaling $2,938 through March 31, 2019.

Indemnification agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements, and therefore it has not accrued any liabilities related to such obligations in its consolidated financial statements as of March 31, 2019 or 2018.

Legal Proceedings

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities.

14. Benefit Plans

The Company established a defined-contribution savings plan under Section 401(k) of the Code (the "401(k) Plan"). The 401(k) Plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Matching contributions to the 401(k) Plan may be made at the discretion of the Company's board of directors. During the years ended March 31, 2019, 2018 and 2017, the Company made contributions totaling $102, $49 and $8, respectively, to the 401(k) Plan.

We provide a pension contribution plan for our employees in the United Kingdom, pursuant to which we match our employees' contributions each year in amounts up to 8% of their annual base salary.

15. Income Taxes

U.S. Tax Reform

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Reform Act"), which significantly reforms the Internal Revenue Code of 1986, as amended (the "Code"). The Tax Reform Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

15. Income Taxes (Continued)

the existing top marginal rate of 35% to a flat rate of 21%, effective as of January 1, 2018; limitation of the deduction for net operating losses to 80% of annual taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such tax losses may be carried forward indefinitely); and modifying or repealing many business deductions and credits.

The staff of the Securities and Exchange Commission issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Reform Act. In connection with the initial analysis of the impact of the Tax Reform Act, the Company remeasured certain deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future, which is generally 21%. The remeasurement of the Company's deferred tax assets and liabilities was offset by a corresponding change in the Company's valuation allowance.

We completed our final determination of the remeasurement of our deferred tax assets and liabilities for the year ended March 31, 2019 under SEC Staff Accounting Bulletin No. 118 and we have not recorded any adjustments to the provisional amounts recorded at March 31, 2018.

Income taxes

During the years ended March 31, 2019, 2018 and 2017, the Company recorded no income tax benefits for the net operating losses incurred and capitalized start-up costs generated during the years then ended, due to its uncertainty of realizing a benefit from those items. The Company's net loss before income taxes were generated in the United States and the United Kingdom.

Net loss before income taxes for the years ended March 31, 2019, 2018 and 2017 were as follows:

	Year Ended March 31,		
	2019	2018	2017
United States	$ (9,483)	$ (8,992)	$ (3,450)
Foreign (United Kingdom)	(21,351)	(10,710)	(4,254)
	$ (30,834)	$ (19,702)	$ (7,704)

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

15. Income Taxes (Continued)

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate for the years ended March 31, 2019, 2018 and 2017 is as follows:

	March 31,		
	2019	2018	2017
U.S. Federal statutory income tax rate	(21.00)%	(21.00)%	(34.00)%
State taxes, net of federal benefit	(1.5)	(2.6)	(2.4)
Research and development expenses	3.1	3.8	7.1
Remeasurement of deferred taxes as a result of tax reform	—	2.6	—
Foreign tax rate differential	2.4	2.2	8.8
Change in valuation allowance	15.5	14.0	19.2
Other	1.5	1.0	1.3
Effective income tax rate	0.00%	0.00%	0.00%

Components of the Company's deferred tax assets as of March 31, 2019 and 2018 were as follows:

	March 31,	
	2019	2018
Deferred tax assets:		
Foreign net operating loss carryforwards	$ 4,079	$ 1,405
Federal net operating loss carryforwards	2,223	—
State net operating loss carryforwards	684	15
Capitalized start-up costs	1,886	3,340
Stock compensation	573	
Accrued expenses	1,793	
Other	—	1
Total deferred tax assets	11,238	4,761
Deferred tax liabilities:		
Property, plant and equipment	(1,842)	(37)
Total deferred tax liabilities	(1,842)	(37)
Valuation allowance	(9,396)	(4,724)
Net deferred tax assets	$ —	$ —

As of March 31, 2019, the Company had federal and foreign net operating loss carryforwards of approximately $10,587 and $23,993 respectively, which can be carried forward indefinitely. As of March 31, 2019, the Company had state net operating loss carryforwards of $10,822 which will expire between 2038 and 2039.

Utilization of the U.S. federal and state net operating loss carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of net operating loss

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

15. Income Taxes (Continued)

carryforwards that can be utilized annually to offset future taxable income and tax liabilities, respectively. The Company has not completed a study to assess whether a change of ownership has occurred, or whether there have been multiple ownership changes since its formation, due to the significant cost and complexity associated with such a study. Any limitation may result in expiration of a portion of the net operating loss carryforwards before utilization. Further, until a study is completed by the Company and any limitation is known, no amounts are being presented as an uncertain tax position.

Changes in the valuation allowance for deferred tax assets during the years ended March 31, 2019 and 2018 related primarily to the increase in net operating loss carryforwards and capitalized start-up costs in 2018, and were as follows:

	March 31,	
	2019	2018
Valuation allowance as of beginning of year	$ 4,724	$ 1,887
Increases recorded to income tax provision	4,672	3,347
Remeasurement of deferred taxes as a result of tax reform	—	(510)
Valuation allowance as of end of year	$ 9,396	$ 4,724

As of March 31, 2019 and 2018, the Company had not recorded any amounts for unrecognized tax benefits. The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision. As of March 31, 2019 and 2018, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts had been recognized in the Company's consolidated statements of operations and comprehensive loss.

The Company files income tax returns in the United States, Massachusetts and the United Kingdom as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by U.S. federal, state and foreign jurisdictions, where applicable. There are currently no pending tax examinations. The Company is open to future tax examination in the U.S. under statute from 2017 to the present and in the United Kingdom from 2016 to the present.

16. Geographic Information

The Company operates in two geographic regions: the United States (Massachusetts) and the United Kingdom (Oxfordshire). Information about the Company's long-lived assets held in different geographic regions is presented in the tables below:

	March 31,	
	2019	2018
United States	$ 11,648	$ 20
United Kingdom	511	350
	$ 12,159	$ 370

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

17. Quarterly Financial Data (Unaudited)

The following information has been derived from unaudited consolidated financial statements that, in the opinion of management, include all recurring adjustments necessary for a fair statement of such information.

	For the Quarter Ended			
	March 31, 2019	December 31, 2018	September 30, 2018	June 30, 2018
Operating expenses	7,825	10,137	7,104	5,879
Net loss	(6,656)	(7,673)	(6,461)	(10,044)
Net loss per share attributable to common shareholders, basic and diluted	(0.29)	(0.24)	(0.26)	(2.02)

	For the Quarter Ended			
	March 31, 2018	December 31, 2017	September 30, 2017	June 30, 2017
Operating expenses	7,065	4,732	4,256	3,176
Net loss	(7,136)	(4,354)	(4,660)	(3,552)
Net loss per share attributable to common shareholders, basic and diluted	(1.43)	(0.87)	(0.94)	(0.71)

18. Subsequent Events

For its consolidated financial statements as of March 31, 2019 and for the year then ended, the Company evaluated subsequent events through the date on which those financial statements were issued.

Lease agreement

In June 2019, the Company entered into an agreement to lease approximately 18,700 square feet of office space in Woburn, Massachusetts. Pursuant to the lease agreement, the lease term is estimated to commence in July 2019. The rent commencement date is to be one month after the commencement of the lease term. The initial lease term is ten years from the rent commencement date and includes an optional five year extension. Annual lease payments during the first year are $488 with increases of approximately 1.6% each year.

Increase in Shares Available for Issuance under the 2018 Plan

In April 2019, the Company effected an increase in the total number of shares of the Company's common stock reserved for issuance under the 2018 Plan from 3,617,968 shares to 4,884,338 shares.

Exhibit 4.3

Description of capital stock

The following description of our capital stock and provisions of our amended and restated certificate of incorporation and bylaws are summaries and are qualified in their entirety by reference to our amended and restated certificate of incorporation and bylaws, and by applicable law, including the DGCL.

Our authorized capital stock consists of 150 million shares of common stock, par value $0.001 per share, and 10 million shares of preferred stock, par value $0.001 per share, all of which shares are undesignated.

Common stock

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock.

Preferred stock

Pursuant to our amended and restated certificate of incorporation, our board of directors has the authority, without further action by our stockholders, to issue up to 10 million shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. There are currently no shares of preferred stock outstanding, and we have no present plan to issue any shares of preferred stock.

Anti-takeover effects of provisions of Delaware law and our amended and restated certificate of incorporation and amended and restated bylaws

Requirements for advance notification of stockholder meetings, nominations and proposals

Our amended and restated certificate of incorporation provides that special meetings of the stockholders may be called only by or at the direction of our board of directors. Our amended and restated bylaws prohibit the conduct of any business at a special meeting other than as specified in the notice for such meeting. These provisions may have the effect of deferring, delaying or discouraging hostile takeovers, or changes in control or management of our company.

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of our board of directors or a committee of our board of directors. In order for any matter to be “properly brought” before a meeting, a stockholder will have to comply with advance notice requirements and provide us with certain information. Additionally, vacancies and newly created directorships may be filled only by a vote of a majority of the directors then in office, even though less than a quorum, and not by the stockholders. Our amended and restated bylaws allow the presiding officer at a meeting of the stockholders to adopt rules and regulations for the conduct of meetings which may have the effect of precluding the conduct of certain business at a meeting if the rules and regulations are not followed. These provisions may also defer, delay or discourage a potential acquirer from conducting a solicitation of proxies to elect the acquirer’s own slate of directors or otherwise attempting to obtain control of our company.

Our amended and restated certificate of incorporation provides that our board of directors is expressly authorized to adopt, amend or repeal our amended and restated bylaws.

No cumulative voting

The DGCL provides that stockholders are not entitled to cumulate votes in the election of directors unless our amended and restated certificate of incorporation provides otherwise. Our amended and restated certificate of incorporation does not expressly provide for cumulative voting.

Amendments to certificate of incorporation and bylaws

The DGCL provides that, unless a corporation's certificate of incorporation provides otherwise, the affirmative vote of holders of shares constituting a majority of the votes of all shares entitled to vote may approve amendments to the certificate of incorporation.

Our amended and rested certificate of incorporation and amended and restated bylaws provide that the affirmative vote of holders of at least 75% of the outstanding shares of capital stock, voting together as a single class, and entitled to vote in the election of directors will be required to amend, alter, change or repeal the amended and restated certificate of incorporation and the amended and restated bylaws. This requirement of a supermajority vote to approve amendments to our amended and restated certificate of incorporation and amended and restated bylaws could enable a minority of our stockholders to exercise veto power over such amendments.

Forum selection clause

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers or other employees to us or our stockholders; (iii) any action asserting a claim against us or any director or officer or other employee of ours arising pursuant to any provision of the DGCL or our amended and restated certificate of incorporation or amended and restated bylaws; or (iv) any action asserting a claim against us or any director or officer or other employee of ours governed by the internal affairs doctrine. Our amended and restated certificate of incorporation further provides that any person or entity that acquires any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions described above. Moreover, our amended and restated certificate of incorporation currently provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. Following a November 2018 decision of the Delaware Court of Chancery, we understand that this provision is invalid. We do not intend to enforce this provision, and we intend to seek the approval of our shareholders at the 2019 annual meeting to amend our certificate of incorporate to remove this provision.

Staggered board

Our amended and restated certificate of incorporation provides that our board of directors is divided into three classes of directors, with the directors in each class serving staggered three-year terms and with the number of directors in each class to be as nearly equal as possible.

Stockholder action by written consent

Pursuant to Section 228 of the DGCL, any action required to be taken at any annual or special meeting of the stockholders may be taken without a meeting, without prior notice and without a vote, if a consent or consents in writing, setting forth the action so taken, is signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares of our stock entitled to vote thereon were present and voted, unless the corporation's certificate of incorporation provides otherwise. Our amended and restated certificate of incorporation prohibits the taking of any action of our stockholders by written consent without a meeting.

Delaware anti-takeover statute

We have not opted out of, and therefore are subject to, Section 203 of the DGCL. Section 203 provides that, subject to certain exceptions specified in the law, a publicly-held Delaware corporation shall not engage in certain "business combinations" with any "interested stockholder" for a three-year period after the date of the transaction in which the person became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (1) shares owned by persons who are directors and also officers and (2) shares owned under employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock. Since Section 203 will apply to us, we expect that it would have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. In such event, we would also anticipate that Section 203 could discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

Under certain circumstances, Section 203 makes it more difficult for a person who would be an "interested stockholder" to effect various business combinations with a corporation for a three-year period. The provisions of Section 203 may encourage companies interested in acquiring our company to negotiate in advance with our board of directors because the stockholder approval requirement would be avoided if our board of directors approves either the business combination or the transaction that results in the stockholder becoming an interested stockholder. These provisions also may make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Authorized but unissued capital stock

The DGCL does not require stockholder approval for any issuance of authorized shares. However, the listing requirements of Nasdaq, which apply so long as our common stock remains listed on Nasdaq, require stockholder approval of certain issuances equal to or exceeding 20% of the then outstanding voting power or then outstanding number of shares of common stock. These additional shares may be used for a variety of corporate purposes, including future public offerings, to raise additional capital or to facilitate acquisitions.

One of the effects of the existence of unissued and unreserved common stock or preferred stock may be to enable our board of directors to issue shares to persons friendly to current management, which issuance could render more difficult or discourage an attempt to obtain control of our company by means of a merger, tender offer, proxy contest or otherwise, and thereby protect the continuity of our management and possibly deprive our investors of opportunities to sell their shares of common stock at prices higher than prevailing market prices.

Registration rights

The holders of approximately 19.2 million shares of our common stock, or their transferees, are entitled to the registration rights with respect to registration of the resale of such shares under the Securities Act pursuant to the amended and restated investors' rights agreement, by and among us and certain of our investors.

Limitations of liability and indemnification

Our amended and restated certificate of incorporation limits the liability of directors to the fullest extent permitted by Delaware law. The effect of these provisions is to eliminate our rights and the rights of our stockholders, through stockholders' derivative

suits on our behalf, to recover monetary damages from a director for breach of fiduciary duty as a director, including breaches resulting from grossly negligent behavior. However, exculpation does not apply to any director if the director has acted in bad faith, knowingly or intentionally violated the law, authorized illegal dividends or redemptions or derived an improper benefit from his or her actions as a director.

In addition, our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by Delaware law. We also expect to continue to maintain directors' and officers' liability insurance. We believe that these indemnification provisions and insurance are useful to attract and retain qualified directors and executive officers.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duty. These provisions may also have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit us and our stockholders.

In addition to the indemnification required in our amended and restated certificate of incorporation and amended and restated bylaws, the we enter into indemnification agreements with each of our directors and executive officers. These agreements provide for the indemnification of our directors and executive officers for all reasonable expenses and liabilities incurred in connection with any action or proceeding brought against them by reason of the fact that they are or were our agents. We believe that these provisions and indemnification agreements, as well as maintaining directors' and officers' liability insurance, help to attract and retain qualified persons as directors and officers.

Market listing

Our common stock is listed on Nasdaq under the symbol "REPL."

Transfer agent and registrar

The transfer agent and registrar for our common stock is Computershare.

Exhibit 10.10

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (this "Agreement") is entered into by and between Replimune, Inc. (the "Company") and Stephen Gorgol (the "Executive") as of May 8, 2019.

WHEREAS, the Company desires to continue to employ the Executive as its Chief Accounting Officer and the Executive desires to continue to serve in such capacity on behalf of the Company;

NOW, THEREFORE, in consideration of the premises and of the mutual covenants and agreements hereinafter set forth, the Company and the Executive hereby agree as follows:

1. Employment.

(a) Term. The initial term of this Agreement shall begin on May 8, 2019, other than the provisions set forth in Section 15, which shall begin ten (10) business days thereafter (as applicable, the "Effective Date") and shall continue for two years, unless the Executive's employment is sooner terminated in accordance with Sections 6, 7, 8, 9, 10, or 11. Unless earlier terminated, the term of this Agreement shall automatically renew for periods of one year unless either party gives the other party written notice at least 90 days prior to the end of the then existing term that the term of this Agreement shall not be further extended. The period commencing on the Effective Date and ending on the date on which the term of this Agreement terminates is referred to herein as the "Term."

(b) Duties. During the Term, the Executive shall continue to serve as the Chief Accounting Officer of the Company, with duties, responsibilities and authority commensurate therewith, and shall continue to report to the Executive Chairman of the Company (the "Chairman"). The Executive shall perform all duties and accept all responsibilities incident to such position as may be reasonably assigned to the Executive by the Chairman. The Executive represents to the Company that the Executive is not subject to or a party to any employment agreement, noncompetition covenant, or other agreement that would be breached by, or prohibit the Executive from, executing this Agreement and performing fully the Executive's duties and responsibilities hereunder.

(c) Best Efforts. During the Term, the Executive shall devote his best efforts and full time and attention to promote the business and affairs of the Company and its affiliated entities, and may be engaged in other business activities only to the extent the Executive has received the prior written consent of the Board of Directors of the Company (the "Board") and such activities do not materially interfere or conflict with the Executive's obligations to the Company hereunder, including, without limitation, obligations pursuant to Section 15 below. The foregoing shall not be construed as preventing the Executive from (1) serving on civic, educational, philanthropic or charitable boards or committees and (2) managing personal investments, so long as such activities are permitted under the Company's code of conduct and employment policies and do not violate the provisions of Section 15 below.

(d) Principal Place of Employment. The Executive understands and agrees that his principal place of employment will be in the Company's offices located in the Boston, MA

metropolitan area and that the Executive will be required to travel for business in the course of performing his duties for the Company.

2. Compensation.

(a) Base Salary. During the Term, the Company shall pay the Executive a base salary ("Base Salary"), at the annual rate of $315,000, which shall be paid in installments in accordance with the Company's normal payroll practices. The Executive's Base Salary shall be reviewed annually by the Chairman pursuant to the normal performance review policies for senior-level executives and may be adjusted from time to time as the Compensation Committee of the Board (the "Compensation Committee") deems appropriate. The Compensation Committee may take any actions of the Board pursuant to this Agreement.

(b) Annual Bonus. The Executive shall be eligible to be awarded an annual discretionary bonus for each fiscal year during the Term, based on the establishment and attainment of individual and corporate performance goals and targets established by the Compensation Committee ("Annual Bonus") in its sole discretion. The target amount of the Executive's Annual Bonus for any fiscal year during the Term is 35% of the Executive's annual Base Salary. Any Annual Bonus awarded shall be paid after the end of the fiscal year to which it relates, at the same time and under the same terms and conditions as the bonuses for other executives of the Company; provided that the Executive must be employed in good standing on the date that Executive's Annual Bonus is paid. The Annual Bonus shall be subject to the terms of the annual bonus plan that is applicable to other executives of the Company, including the requirement as to continued employment in good standing, subject to the provisions of Section 7 below.

3. Retirement and Welfare Benefits. During the Term, the Executive shall be eligible to participate in the Company's health, life insurance, long-term disability, retirement and welfare benefit plans and programs available to similarly-situated employees of the Company, pursuant to their respective terms and conditions. Nothing in this Agreement shall preclude the Company or any Affiliate of the Company from terminating or amending any employee benefit plan or program from time to time after the Effective Date.

4. Paid Time Off. During the Term, the Executive shall be entitled to five weeks of paid time off, in accordance with the Company's paid time off policy, as may in effect from time to time. The Executive may use paid time off for vacation, personal time, or sick time (in accordance with applicable law).

5. Business Expenses. The Company shall reimburse the Executive for all necessary and reasonable travel (which does not include commuting) and other business expenses incurred by the Executive in the performance of his duties hereunder in accordance with such policies and procedures as the Company may adopt generally from time to time for executives.

6. Termination Without Cause; Resignation for Good Reason. The Company may terminate the Executive's employment at any time without Cause (as defined below) upon 30 days' advance written notice. The Executive may initiate a termination of employment by resigning without Cause or for Good Reason (as defined below) as described below. Upon termination by

the Company without Cause or resignation by the Executive for Good Reason before or after the Change in Control Protection Period (as defined below), if the Executive executes and does not revoke a written Release (as defined below), the Executive shall be entitled to receive, in lieu of any payments under any severance plan or program for employees or executives, the following:

(a) The Company will pay the Executive an amount equal to 0.75 times the Executive's annual Base Salary. Payment shall be made over the nine-month period following the termination date in installments in accordance with the Company's normal payroll practices. Payment will begin within 60 days following the termination date, and any installments not paid between the termination date and the date of the first payment will be paid with the first payment.

(b) The Company shall make a lump-sum payment within 60 days following the termination date equal to the COBRA premiums that the Executive would pay if he elected continued health coverage under the Company's health plan for the Executive and his dependents for the nine-month period following the termination date, based on the COBRA rates in effect at the termination date.

(c) The Company shall pay any other amounts earned, accrued and owing but not yet paid under Section 2 above and any benefits accrued and due under any applicable benefit plans and programs of the Company ("Accrued Obligations"), regardless of whether the Executive executes or revokes the Release.

7. Change of Control Termination. Notwithstanding the foregoing, upon termination by the Company without Cause or resignation by the Executive for Good Reason, in each case on or within 12 months following a Change of Control (as defined in the Replimune Group, Inc. 2018 Omnibus Incentive Compensation Plan, as in effect from time to time, or a successor plan) (the "Change of Control Protection Period"), and provided that the Executive executes and does not revoke a written Release, then the Executive shall be entitled to receive, in lieu of any payments under Section 6 of this Agreement or any severance plan or program for employees or executives, the following:

(a) The Company will pay the Executive an amount equal to the sum of (x) the Executive's annual Base Salary, plus (y) the Executive's target Annual Bonus for the year of termination. Payment shall be made over the 12-month period following the termination date in installments in accordance with the Company's normal payroll practices. Payment will begin within 60 days following the termination date, and any installments not paid between the termination date and the date of the first payment will be paid with the first payment.

(b) The Company shall make a lump-sum payment within 60 days following the termination date equal to the COBRA premiums that the Executive would pay if he elected continued health coverage under the Company's health plan for the Executive and his dependents for the 12-month period following the termination date, based on the COBRA rates in effect at the termination date.

(c) The Company shall pay any Accrued Obligations, regardless of whether the Executive executes or revokes the Release.

8. Cause. The Company may immediately terminate the Executive's employment at any time for Cause upon written notice to the Executive, in which event all payments under this Agreement shall cease, except for any Accrued Obligations.

9. Voluntary Resignation Without Good Reason. The Executive may voluntarily terminate employment without Good Reason upon 30 days' prior written notice to the Company. In such event, after the effective date of such termination, no payments shall be due under this Agreement, except that the Executive shall be entitled to any Accrued Obligations.

10. Disability. If the Executive incurs a Disability during the Term, in accordance with applicable law, the Company may terminate the Executive's employment on or after the date of Disability. If the Executive's employment terminates on account of Disability, the Executive shall be entitled to receive any Accrued Obligations. For purposes of this Agreement, the term "Disability" shall mean the Executive is eligible to receive long-term disability benefits under the Company's long-term disability plan.

11. Death. If the Executive dies during the Term, the Executive's employment shall terminate on the date of death and the Company shall pay to the Executive's executor, legal representative, administrator or designated beneficiary, as applicable, any Accrued Obligations. Otherwise, the Company shall have no further liability or obligation under this Agreement to the Executive's executors, legal representatives, administrators, heirs or assigns or any other person claiming under or through the Executive.

12. Resignation of Positions. Effective as of the date of any termination of employment, the Executive will resign from all Company-related positions, including as an officer and director of the Company and its parents, subsidiaries and Affiliate, as applicable, and shall execute all documentation necessary to effectuate such resignation(s).

13. Definitions. For purposes of this Agreement, the following terms shall have the following meanings:

(a) "Cause" shall mean a determination by the Board that the Executive (1) has breached this Agreement or any confidentiality, nonsolicitation, noncompetition or inventions assignment agreement or obligations with the Company; (2) committed an act of dishonesty, fraud, embezzlement or theft; (3) engaged in conduct that causes, or is likely to cause, material damage to the property or reputation of the Company; (4) failed to perform satisfactorily the material duties of the Executive's position (other than by reason of Disability) after receipt of a written warning from the Board; (5) committed a felony or any crime of moral turpitude; or (6) materially failed to comply with the Company's code of conduct or employment policies.

(b) "Good Reason" shall mean the occurrence of one or more of the following without the Executive's consent, other than on account of the Executive's Disability:

(1) A material diminution by the Company of the Executive's authority, duties or responsibilities;

(2) A material change in the geographic location at which the Executive must perform services under this Agreement (which, for purposes of this Agreement, means relocation

of the offices of the Company at which the Executive is principally employed to a location that increases the Executive's commute to work by more than 50 miles);

(3) A material diminution in the Executive's Base Salary, other than a general reduction in Base Salary that affects all similarly-situated executives in substantially the same proportions;

(4) Any action or inaction that constitutes a material breach by the Company of this Agreement; or

(5) The Company elects not to renew the Term of this Agreement at the end of the Term pursuant to Section 1(a) above for any reason other than Cause or Disability and does not offer the Executive continued employment on substantially similar terms as set forth in this Agreement.

The Executive must provide written notice of termination for Good Reason to the Company within 30 days after the event constituting Good Reason. The Company shall have a period of 30 days in which it may correct the act or failure to act that constitutes the grounds for Good Reason as set forth in the Executive's notice of termination. If the Company does not correct the act or failure to act, the Executive's employment will terminate for Good Reason on the first business day following the Company's 30-day cure period. If the Executive does not provide written notice of termination for Good Reason to the Company within 30 days after an event constituting Good Reason, then the Executive will be deemed to have waived the Executive's right to terminate for Good Reason with respect to such event.

(c) "Release" shall mean a separation agreement and general release of any and all claims against the Company and all related parties with respect to all matters arising out of the Executive's employment by the Company, and the termination thereof (other than claims for any entitlements under the terms of this Agreement or under any plans or programs of the Company under which the Executive has accrued and is due a benefit). The Release will be in a standard form acceptable to the Company.

14. Section 409A.

(a) This Agreement is intended to comply with section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), and its corresponding regulations, or an exemption thereto, and payments may only be made under this Agreement upon an event and in a manner permitted by section 409A of the Code, to the extent applicable. Severance benefits under this Agreement are intended to be exempt from section 409A of the Code under the "short-term deferral" exception, to the maximum extent applicable, and then under the "separation pay" exception, to the maximum extent applicable. Notwithstanding anything in this Agreement to the contrary, if required by section 409A of the Code, if the Executive is considered a "specified employee" for purposes of section 409A of the Code and if payment of any amounts under this Agreement is required to be delayed for a period of six months after separation from service pursuant to section 409A of the Code, payment of such amounts shall be delayed as required by section 409A of the Code, and the accumulated amounts shall be paid in a lump-sum payment within 10 days after the end of the six-month period. If the Executive dies during the

postponement period prior to the payment of benefits, the amounts withheld on account of section 409A of the Code shall be paid to the personal representative of the Executive's estate within 60 days after the date of the Executive's death.

(b) All payments to be made upon a termination of employment under this Agreement may only be made upon a "separation from service" under section 409A of the Code. For purposes of section 409A of the Code, each payment hereunder shall be treated as a separate payment, and the right to a series of installment payments under this Agreement shall be treated as a right to a series of separate payments. In no event may the Executive, directly or indirectly, designate the fiscal year of a payment. Notwithstanding any provision of this Agreement to the contrary, in no event shall the timing of the Executive's execution of the Release, directly or indirectly, result in the Executive's designating the fiscal year of payment of any amounts of deferred compensation subject to section 409A of the Code, and if a payment that is subject to execution of the Release could be made in more than one taxable year, payment shall be made in the later taxable year.

(c) All reimbursements and in-kind benefits provided under this Agreement shall be made or provided in accordance with the requirements of section 409A of the Code, including, where applicable, the requirement that (i) any reimbursement be for expenses incurred during the period specified in this Agreement, (ii) the amount of expenses eligible for reimbursement, or in-kind benefits provided, during a fiscal year not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other fiscal year, (iii) the reimbursement of an eligible expense be made no later than the last day of the fiscal year following the year in which the expense is incurred, and (iv) the right to reimbursement or in-kind benefits not be subject to liquidation or exchange for another benefit.

15. Restrictive Covenants.

(a) Noncompetition. The Executive agrees that during the Executive's employment with the Company and its Affiliates and the one-year period following the date on which the Executive's employment terminates for any reason (the "Restriction Period"), the Executive will not, without the Board's express written consent, engage (directly or indirectly) in any Competitive Business in the Restricted Area. The term "Competitive Business" means any activities or services conducted by any third party with respect to the research, development, marketing, manufacturing or sale of oncolytic immunotherapies that are similar to the activities or services the Executive has performed at any time during the last two years of Executive's employment with the Company. The term "Restricted Area" means the United States of America, Canada and countries within Europe, in respect of which the Company or any of its Affiliates has material business operations as of the date on which the Executive's employment terminates and in which the Executive has provided services or had a material presence or influence at any time during the last two years of the Executive's employment with the Company or its Affiliates. The Executive agrees that the increase in Base Salary provided for in Section 2(a), the increase in Annual Bonus percentage opportunity provided for in Section 2(b), the separation benefits provided for in Section 6 and the Change of Control Termination benefits provided for in Section 7, are fair and reasonable consideration for Executive's compliance with this Section 15(a). The Executive understands and agrees that, given the nature of the business of the Company and its Affiliates (as defined below) and the Executive's position with the

Company, the foregoing geographic scope is reasonable and appropriate and that more limited geographical limitations on this non-competition covenant are therefore not appropriate. For purposes of this Agreement, the term "Affiliate" means the Company's sole shareholder, any subsidiary of the Company or other entity under common control with the Company. The Company shall not enforce this Section 15(a) if it terminates my employment without Cause as defined in Section 13(a).

(b) Nonsolicitation of Company Personnel. The Executive agrees that during the Restriction Period, the Executive will not, either directly or through others, hire or attempt to hire any employee, consultant or independent contractor of the Company or its Affiliates, or solicit or attempt to solicit any such person to change or terminate his or her relationship with the Company or an Affiliate or otherwise to become an employee, consultant or independent contractor to, for or of any other person or business entity, unless more than 12 months shall have elapsed between the last day of such person's employment or service with the Company or Affiliate and the first day of such solicitation or hiring or attempt to solicit or hire. If any employee, consultant or independent contractor is hired or solicited by any entity that has hired or agreed to hire the Executive, such hiring or solicitation shall be conclusively presumed to be a violation of this subsection (b).

(c) Nonsolicitation of Business Partners. The Executive agrees that during the Restriction Period, the Executive will not, either directly or through others, solicit, divert or appropriate, or attempt to solicit, divert or appropriate for the benefit of a Competitive Business, any (1) business partner or (2) prospective business partner of the Company or an Affiliate who is or was identified through leads developed during the course of the Executive's employment or service with the Company, in each case, with whom the Executive was involved as part of the Executive's job responsibilities during the Executive's employment or service with the Company, or regarding whom the Executive learned Proprietary Information during the Executive's employment or service with the Company.

(d) Proprietary Information. At all times, the Executive will hold in strictest confidence and will not disclose, use, lecture upon or publish any of the Proprietary Information (defined below) of the Company or an Affiliate, except as such disclosure, use or publication may be required in connection with the Executive's work for the Company or as described in Section 15(e) below, or unless the Company expressly authorizes such disclosure in writing. "Proprietary Information" shall mean any and all confidential and/or proprietary knowledge, data or information of the Company and its Affiliates and shareholders, including but not limited to information relating to financial matters, investments, budgets, business plans, marketing plans, personnel matters, business contacts, products, processes, know-how, designs, methods, improvements, discoveries, inventions, ideas, data, programs, and other works of authorship. Proprietary Information does not include information which (1) was disclosed in response to a valid order by a court or other governmental body, where the Executive provided the Company with prior written notice of such disclosure, (2) was or becomes generally available to the public other than as a result of disclosure by the Executive or any of the Executive's agents, advisors or representatives, (3) was within the Executive's possession prior to its being furnished to the Executive by or on behalf of the Company, provided that the source of the information was not bound by a confidentiality agreement with the Company or otherwise prohibited from transmitting the information to Executive by a contractual, legal or fiduciary obligation, or (4)

was or becomes available to the Executive on a non-confidential basis from a source other than the Company or its representatives, provided that such source is not bound by a confidentiality agreement with the Company or otherwise prohibited from transmitting the information to the Executive by a contractual, legal or fiduciary obligation.

(e) Reports to Government Entities. Nothing in this Agreement shall prohibit or restrict the Executive from initiating communications directly with, responding to any inquiry from, providing testimony before, providing confidential information to, reporting possible violations of law or regulation to, or filing a claim or assisting with an investigation directly with a self-regulatory authority or a government agency or entity, including the Equal Employment Opportunity Commission, the Department of Labor, the National Labor Relations Board, the Department of Justice, the Securities and Exchange Commission, Congress, any agency Inspector General or any other federal, state or local regulatory authority (collectively, the "Regulators"), or from making other disclosures that are protected under the whistleblower provisions of state or federal law or regulation. The Executive does not need the prior authorization of the Company to engage in conduct protected by this subsection, and the Executive does not need to notify the Company that the Executive has engaged in such conduct. Please take notice that federal law provides criminal and civil immunity to federal and state claims for trade secret misappropriation to individuals who disclose trade secrets to their attorneys, courts, or government officials in certain, confidential circumstances that are set forth at 18 U.S.C. §§ 1833(b)(1) and 1833(b)(2), related to the reporting or investigation of a suspected violation of the law, or in connection with a lawsuit for retaliation for reporting a suspected violation of the law.

(f) Work Made for Hire; Inventions Assignment. The Executive agrees that all inventions, innovations, improvements, developments, methods, designs, analyses, reports, and all similar or related information which relates to the Company's or its Affiliates' actual or anticipated business, research and development or existing or future products or services and which are conceived, developed or made by the Executive while employed by the Company ("Work Product") belong to the Company. The Executive acknowledges that, by reason of being employed by the Company at the relevant times, to the extent permitted by law, all of the Work Product consisting of copyrightable subject matter is "work made for hire" as defined in 17 U.S.C. § 101 and such copyrights are therefore owned by the Company. To the extent that the foregoing does not apply, the Executive hereby irrevocably assigns to the Company, for no additional consideration, the Executive's entire right, title, and interest in and to all Work Product and intellectual property rights therein, including, without limitation, the right to sue, counterclaim, and recover for all past, present, and future infringement, misappropriation, or dilution thereof, and all rights corresponding thereto throughout the world. The Executive will promptly disclose such Work Product to the Board and perform all actions reasonably requested by the Board (whether during or after the Term) to establish and confirm such ownership (including, without limitation, executing assignments, consents, powers of attorney and other instruments). If requested by the Company, the Executive agrees to execute any inventions assignment and confidentiality agreement that is required to be signed by Company employees generally. Nothing contained in this Agreement shall be construed to reduce or limit the Company's rights, title, or interest in any Work Product or intellectual property rights so as to be less in any respect than that the Company would have had in the absence of this Agreement. The Executive understands that this Agreement does not, and shall not be construed to, grant the

Executive any license or right of any nature with respect to any Work Product or intellectual property rights or any Proprietary Information, materials, software, or other tools made available to the Executive by the Company.

(g) Return of Company Property. Upon termination of the Executive's employment with the Company for any reason, and at any earlier time the Company requests, the Executive will (1) deliver to the person designated by the Company all originals and copies of all documents and property of the Company or an Affiliate that is in the Executive's possession or under the Executive's control or to which the Executive may have access, (2) deliver to the person designated by the Company all Company property, including keys, key cards, access cards, identification cards, security devices, employer credit cards, network access devices, computers, cell phones, smartphones, PDAs, pagers, fax machines, equipment, manuals, reports, files, books, compilations, work product, e-mail messages, recordings, disks, thumb drives or other removable information storage devices, hard drives, and data, and (3) to the extent that the Executive made use of the Executive's personal electronics (e.g., laptop, iPad, telephone, thumb drives, etc.) during employment with the Company, permit the Company to delete all Company property and information from such personal devices. The Executive will not reproduce or appropriate for the Executive's own use, or for the use of others, any property, Proprietary Information or Work Product.

16. Legal and Equitable Remedies.

(a) Because the Executive's services are personal and unique and the Executive has had and will continue to have access to and has become and will continue to become acquainted with the Proprietary Information of the Company and its Affiliates, and because any breach by the Executive of any of the restrictive covenants contained in Section 15 would result in irreparable injury and damage for which money damages would not provide an adequate remedy, the Company shall have the right to enforce Section 15 and any of its provisions by injunction, specific performance or other equitable relief, without bond and without prejudice to any other rights and remedies that the Company may have for a breach, or threatened breach, of the restrictive covenants set forth in Section 15. The Executive agrees that in any action in which the Company seeks injunction, specific performance or other equitable relief, the Executive will not assert or contend that any of the provisions of Section 15 are unreasonable or otherwise unenforceable.

(b) The Executive irrevocably and unconditionally (1) agrees that any legal proceeding arising out of this Agreement shall be brought solely in the United States District Court for the District of Massachusetts, or if such court does not have jurisdiction or will not accept jurisdiction, in any court of general jurisdiction in the State of Massachusetts, (2) consents to the exclusive jurisdiction of such court in any such proceeding, and (3) waives any objection to the laying of venue of any such proceeding in any such court. The Executive also irrevocably and unconditionally consents to the service of any process, pleadings, notices or other papers.

(c) Notwithstanding anything in this Agreement to the contrary, if the Executive breaches any of the Executive's obligations under Section 15, the Company shall be obligated to provide only the Accrued Obligations, and all payments under Section 2, Section 6, or Section 7 hereof, as applicable, shall cease. In such event, and in addition to any legal and equitable

remedies permitted by law, the Company may require that the Executive repay all amounts theretofore paid to him pursuant to Sections 6 and 7 hereof (other than Sections 6(c) and 7(c)), and in such case, the Executive shall promptly repay such amounts on the terms determined by the Company.

17. Survival. The respective rights and obligations of the parties under this Agreement (including, but not limited to, under Sections 15 and 16) shall survive any termination of the Executive's employment or termination or expiration of this Agreement to the extent necessary to the intended preservation of such rights and obligations.

18. No Mitigation or Set-Off. In no event shall the Executive be obligated to seek other employment or take any other action by way of mitigation of the amounts payable to the Executive under any of the provisions of this Agreement, and such amounts shall not be reduced regardless of whether the Executive obtains other employment. The Company's obligation to make the payments provided for in this Agreement and otherwise to perform its obligations hereunder shall not be affected by any circumstances, including, without limitation, any set-off, counterclaim, recoupment, defense or other right which the Company may have against the Executive or others.

19. Section 280G. In the event of a change in ownership or control under section 280G of the Code, if it shall be determined that any payment or distribution in the nature of compensation (within the meaning of section 280G(b)(2) of the Code) to or for the benefit of the Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (a "Payment"), would constitute an "excess parachute payment" within the meaning of section 280G of the Code, the aggregate present value of the Payments under the Agreement shall be reduced (but not below zero) to the Reduced Amount (defined below) if and only if the Accounting Firm (described below) determines that the reduction will provide the Executive with a greater net after-tax benefit than would no reduction. No reduction shall be made unless the reduction would provide Executive with a greater net after-tax benefit. The determinations under this Section shall be made as follows:

(a) The "Reduced Amount" shall be an amount expressed in present value which maximizes the aggregate present value of Payments under this Agreement without causing any Payment under this Agreement to be subject to the Excise Tax (defined below), determined in accordance with section 280G(d)(4) of the Code. The term "Excise Tax" means the excise tax imposed under section 4999 of the Code, together with any interest or penalties imposed with respect to such excise tax.

(b) Payments under this Agreement shall be reduced on a nondiscretionary basis in such a way as to minimize the reduction in the economic value deliverable to the Executive. Where more than one payment has the same value for this purpose and they are payable at different times, they will be reduced on a pro rata basis. Only amounts payable under this Agreement shall be reduced pursuant to this Section.

(c) All determinations to be made under this Section shall be made by an independent certified public accounting firm selected by the Company and agreed to by the Executive immediately prior to the change-in-ownership or -control transaction (the "Accounting Firm").

The Accounting Firm shall provide its determinations and any supporting calculations both to the Company and the Executive within 10 days of the transaction. Any such determination by the Accounting Firm shall be binding upon the Company and the Executive. All of the fees and expenses of the Accounting Firm in performing the determinations referred to in this Section shall be borne solely by the Company.

20. Notices. All notices and other communications required or permitted under this Agreement or necessary or convenient in connection herewith shall be in writing and shall be deemed to have been given when hand delivered or mailed by registered or certified mail, as follows (provided that notice of change of address shall be deemed given only when received):

If to the Company, to:

Replimune Inc.
18 Commerce Way
Woburn, MA 01801
Attn: Executive Chairman

with a copy to:

Morgan, Lewis & Bockius LLP
One Federal Street
Boston, MA 02110
Attn: Gitte Blanchet

If to the Executive, to the most recent address on file with the Company or to such other names or addresses as the Company or the Executive, as the case may be, shall designate by notice to each other person entitled to receive notices in the manner specified in this Section.

21. Withholding. All payments under this Agreement shall be made subject to applicable tax withholding, and the Company shall withhold from any payments under this Agreement all federal, state and local taxes as the Company is required to withhold pursuant to any law or governmental rule or regulation. The Executive shall bear all expense of, and be solely responsible for, all federal, state and local taxes due with respect to any payment received under this Agreement.

22. Remedies Cumulative; No Waiver. No remedy conferred upon a party by this Agreement is intended to be exclusive of any other remedy, and each and every such remedy shall be cumulative and shall be in addition to any other remedy given under this Agreement or now or hereafter existing at law or in equity. No delay or omission by a party in exercising any right, remedy or power under this Agreement or existing at law or in equity shall be construed as a waiver thereof, and any such right, remedy or power may be exercised by such party from time to time and as often as may be deemed expedient or necessary by such party in its sole discretion.

23. Assignment. All of the terms and provisions of this Agreement shall be binding upon and inure to the benefit of and be enforceable by the respective heirs, executors, administrators, legal

representatives, successors and assigns of the parties hereto, except that the duties and responsibilities of the Executive under this Agreement are of a personal nature and shall not be assignable or delegable in whole or in part by the Executive. The Company may assign its rights, together with its obligations hereunder, in connection with any sale, transfer or other disposition of all or substantially all of its business and assets, and such rights and obligations shall inure to, and be binding upon, any successor to the business or any successor to substantially all of the assets of the Company, whether by merger, purchase of stock or assets or otherwise, which successor shall expressly assume such obligations, and the Executive acknowledges that in such event the obligations of the Executive hereunder, including but not limited to those under Section 15, will continue to apply in favor of the successor.

24. Company Policies. This Agreement and the compensation payable hereunder shall be subject to any applicable clawback or recoupment policies, share trading policies, and other policies that may be implemented by the Board from time to time with respect to officers of the Company.

25. Indemnification. In the event the Executive is made, or threatened to be made, a party to any legal action or proceeding, whether civil or criminal, including any governmental or regulatory proceedings or investigations, by reason of the fact that the Executive is or was a director or officer of the Company or any of its Affiliates, the Executive shall be indemnified by the Company, and the Company shall pay the Executive's related expenses when and as incurred, to the fullest extent permitted by applicable law and the Company's articles of incorporation and bylaws. During the Executive's employment with the Company or any of its Affiliates and after termination of employment for any reason, the Company shall cover the Executive under the Company's directors' and officers' insurance policy applicable to other officers and directors according to the terms of such policy.

26. Entire Agreement; Amendment. This Agreement sets forth the entire agreement of the parties hereto and supersedes any and all prior agreements and understandings concerning the Executive's employment by the Company, including, without limitation, the offer letter dated August 9, 2016 from the Company to the Executive; provided, however that the Replimune, Inc. At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement, dated July 13, 2017, shall continue in full force and effect and the terms of which are hereby incorporated by reference. This Agreement may be changed only by a written document signed by the Executive and the Company.

27. Severability. If any provision of this Agreement or application thereof to anyone or under any circumstances is adjudicated to be invalid or unenforceable in any jurisdiction, such invalidity or unenforceability shall not affect any other provision or application of this Agreement, which can be given effect without the invalid or unenforceable provision or application, and shall not invalidate or render unenforceable such provision or application in any other jurisdiction. If any provision is held void, invalid or unenforceable with respect to particular circumstances, it shall nevertheless remain in full force and effect in all other circumstances.

28. Governing Law. This Agreement shall be governed by, and construed and enforced in accordance with, the substantive and procedural laws of Massachusetts without regard to rules governing conflicts of law.

29. Counterparts. This Agreement may be executed in any number of counterparts (including facsimile counterparts), each of which shall be an original, but all of which together shall constitute one instrument.

(Signature Page Follows)

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

REPLIMUNE, INC.

/s/ Philip Astley-Sparke
Name: Philip Astely-Sparke
Title: Executive Chairman
Date: 8 May 2019

EXECUTIVE

/s/ Stephen Gorgol
Name: Stephen Gorgol

Date: May 8, 2019

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-226323) of Replimune Group, Inc. of our report dated June 28, 2019 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
June 28, 2019

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Exhibit 31.1

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Robert Coffin, certify that:

1. I have reviewed this Annual Report on Form 10-K of Replimune Group, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: June 28, 2019

By: /s/ ROBERT COFFIN

Robert Coffin, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

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Exhibit 31.2

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Stephen Gorgol, certify that:

1. I have reviewed this Annual Report on Form 10-K of Replimune Group, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: June 28, 2019

By: /s/ STEPHEN GORGOL

Stephen Gorgol
Chief Accounting Officer
(Principal Financial Officer)

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Exhibit 32.1

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Replimune Group, Inc. (the "Company") for the fiscal year ended March 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Robert Coffin, Ph.D., President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: June 28, 2019

By: /s/ ROBERT COFFIN

Robert Coffin, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

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Exhibit 32.2

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Replimune Group, Inc. (the "Company") for the fiscal year ended March 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Stephen Gorgol, Chief Accounting Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: June 28, 2019

By: /s/ STEPHEN GORGOL

Stephen Gorgol
Chief Accounting Officer
(Principal Financial Officer)

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